THESIS

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DOCTOR OF SURGERY

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A COMPARATIVE STUDY OF CONVENTIONAL DAILY VERSUS LOW DOSE WEEKLY ORAL IRON SUPPLEMENTATION IN PREVENTING ANEMIA DURING PREGNANCY

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Date **Dr. Shams Jahan**

Place

ABBREVIATION

IDA- Iron deficiency anemia

ID- Iron depletion

Hb – hemoglobin

WHO- World health Organization

FIGO- International Federation of Obstetrics& Gynecology

µgm- Micrograms

mg- Milligram

kg- Kilogram

e.g- example

RBCs- Red blood cell

RhEPO- recombinant human erythropoietin

RES- Reticulo endothelial system

TIBC- Total iron binding capacity

dl- deciliter

NFHS- National family health survey

UNICEF- United Nations International Children's Emergency Fund

FOGSI- Federation of Obstetrics and Gynecological societies of India

NNAPP- National Nutritional Anemia Prophylaxis Programme

INACG-International Nutritional Anemia Consultative Group

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INTRODUCTION

Iron deficiency continues to be the leading cause of single-nutrient deficiency in the world, affecting the lives of > 2 billion persons although considerable efforts are done to decrease its prevalence for the past 3 decades. Nutritional iron deficiency is seen highest in populations which are at peak rates of growth mainly infants, young children, and pregnant women[1]. In India 62-88% pregnant women suffer from anemia. Approximately 80% of all anemia cases in pregnancy occur due to iron deficiency[2].

The iron requirement during pregnancy is drastically more than that in the non-pregnant state despite the temporary break from iron losses which occur during menstruation in non pregnant state[1]. Pregnant women require supplementary iron and folic acid to meet their own nutritional needs as well as those of the developing fetus[3]. Iron requirements increase especially from second trimester of pregnancy onwards due to the increase in the red blood cell volume and the transfer of greater amounts of iron to both the growing fetus and the placenta. Iron is also wasted due to bleeding and lochia at the time of delivery as well as during puerperium. The increased requirements can be fulfilled provided the storage form of iron at the start of pregnancy is sufficient and also there is availability of enough amounts of dietary iron that can be absorbed during pregnancy. Iron deficiency anemia usually develops during pregnancy which indicates that the physiologic adaptations are seldom sufficient to meet the increased requirements. Hence supplementing iron during pregnancy is a universal practice throughout the world[1].

Deficiencies in iron and folic acid during pregnancy can potentially negatively impact the health of the mother, her pregnancy, as well as fetal development[3]. In the mother, iron deficiency & iron deficiency anemia (IDA) have been associated with preeclampsia, preterm delivery, and even miscarriage, and in the child with fetal growth restriction and impaired cognitive functions and many other complications. Furthermore, some studies have underscored the importance of timing of ID and IDA, since some long–term consequences, especially regarding the development and functioning of the child's brain, are irreversible, even after correcting iron levels. As a result, it is essential to maintain good nutritional care even before getting pregnant,

as well as throughout the whole gestation, to ensure an optimal health status for mother and baby[4].

Although daily iron and folic acid are provided free or cheaply in most countries, the major problem is none or poor compliance. This might be due to personal behaviors, cultural issues, and environmental factors, lack of awareness, socio-demographic status, economic factors, inadequate service delivery or side-effects. Unpleasant side-effects of iron such as constipation, diarrhea, gastric cramping, nausea, vomiting, metallic taste and black colored stool also decrease the compliance in patients[5].

The use of daily intake of iron and folic acid throughout pregnancy has been the standard approach to prevent and treat iron deficiency anemia. Despite its proven efficacy, the use of daily iron supplementation has achieved limited success in program settings, may be due to less compliance as well as concerns for the safety of iron overload among women with an adequate iron intake, and erratic availability of the supplements at community level. Studies have shown that intermittent regimens may be more accepted by women, with amplified devotion to supplementation programs[6].

This study is being conducted to establish whether weekly antenatal oral iron and folic acid supplementation is an effective alternative to a daily regimen in non anemic pregnant women in preventing anemia and iron deficiency during pregnancy.

AIM & OBJECTIVES

The study "**A comparative study of conventional daily versus low dose weekly oral iron supplementation in preventing anemia during pregnancy**" was conducted with following objectives:

- To find out the usefulness of daily versus weekly oral iron regimen.
- To compare the overall pregnancy outcome of daily versus weekly oral iron supply with reference to

1) Haemoglobin level
2) Serum ferritin
3) Side effects
4) Compliance of the pregnant women.

REVIEW OF LITERATURE

Anemia is a derivative of a Greek word, without (an) blood (heme) meaning "No blood". Anemia is reduction in total circulating Erythrocyte mass below the critical level which leads to decreased oxygen carrying capacity of blood, which in turn leads to hypoxia.

International Federation of Obstetric and Gynecological Society (FIGO) defines anemia as hemoglobin less than 10g/dl. Centre of Disease Control recommends a cut-off point of 10.5 g/dl hemoglobin during the second trimester and <11 g/dl in first and third trimester[7].

Anemia is a global problem. It is a direct cause of 5-25% of maternal death and indirect cause in 20%-40% of maternal deaths. The overall prevalence of anemia during pregnancy is estimated by the World Health Organization (WHO) to be 47.4%. According to recent WHO figures, India is included in the list of countries with high occurrence of anemia in pregnant women (>40%). The relative risk of maternal mortality due to moderate anemia was 1.35 and for severe anemia is 3.51[8].

The risk of maternal mortality increases 8-10 fold when hemoglobin falls <5 g/dl. Iron deficiency anemia is one of the leading nutritional disorders and presents as a widespread public health problem in the world and especially in developing countries including India[2].

Total requirements of iron in pregnancy differ with the body weight of the mother and the size and maturity of the foetus. In an average, demands for iron in pregnancy come to a total of around 900 mg (700-1400 mg)[9]. Uterus and its contents-500 to 600; Blood loss at delivery -150 to 200 mg ; Red cells mass expansion -500 mg; average saving due to amenorrhea -225 mg; iron deficit -600 to 700mg. Requirements are 4mg/day approximately (2.5 mg/day in early pregnancy, 5.5 mg/day in 20-32 week/ 6-8 mg/day from 32 weeks onwards). As absorption is around 10%, for 4-6 mg absorption of iron 40-60 mg of iron should be available in the diet[9].

Pathophysiology of Anemia:

Haematopoiesis is the production of circulating erythrocytes and others blood components from stem cells. Over 200 billion cells are produced daily in a normal person this way and in larger numbers in people with anemia or iron deficiencies. Haematopoietic system mainly in bone marrow in adults and requirements are iron, vitamin B12, folic acid and growth factors.

Inadequate supply of any of this leads to anemia[10].

Iron metabolism:

Body has an extended system for the supply of Iron for haematopoiesis which requires specialised transport and storage proteins according to body's demand[10].

Table 1- Allocation of Iron in human body

	IRON CONTENT(mg)	
	Men	Women
Haemoglobin	2500	1700
Myoglobin / Enzymes	500	300
Transferrin	3	3
Iron stores	600 – 1000	0 – 300

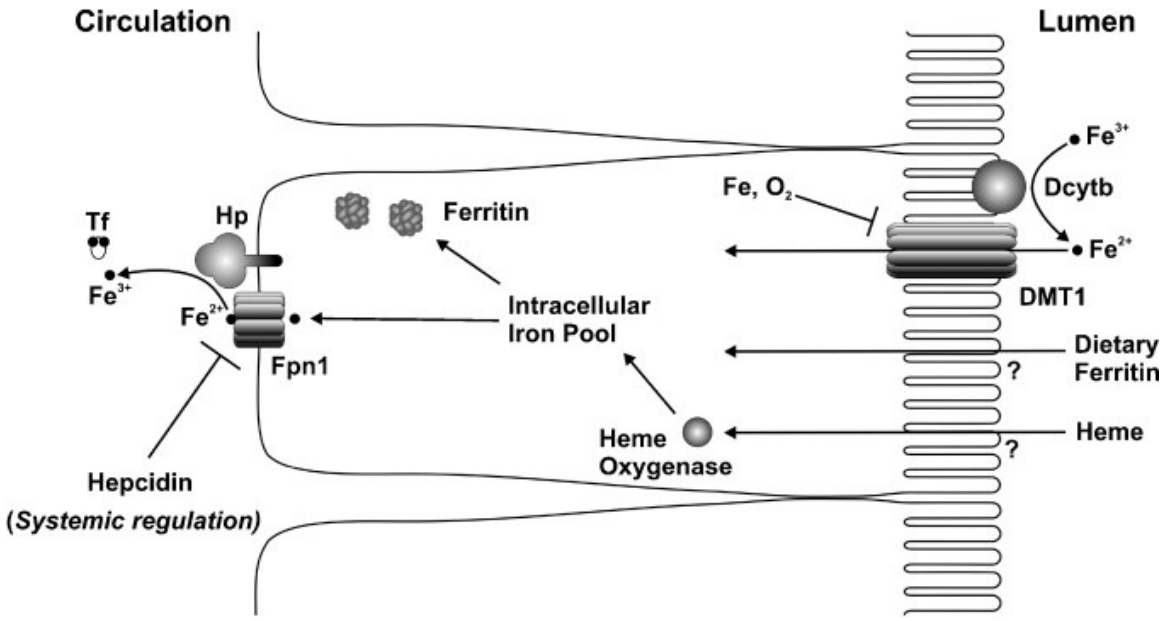
*(Values are based on data from various sources and assume that normal man weight 80 kg and normal woman weight 60 kg).

Majority of Iron used for haematopoiesis is recovered from the catalysis of old erythrocytes and only a small iron is lost each day. So dietary requirements are small for iron easily replenished by different foods but in special population where iron is required more (e.g. growing children, pregnant woman, lactating mother) or increased losses e.g. menstruating woman iron requirements exceeds normal dietary supply thereby causing iron deficiency anemia[10].

The process of iron absorption is dependent on the body iron stores and the activity of haematopoietic system. Low stores of iron and increased haematopoiesis causes more of intestinal iron absorption where as normal iron stores and decreased haematopoiesis result in decreased iron absorption. The iron stored in erythrocytes as haemoglobin and in muscles in myoglobin. A very small amount of iron is attached to transport protein called transferrin though majority of iron stored in liver and bone marrow attached to ferritin[11].

Iron is absorbed through intestinal brush border of enterocytes in proximal small intestine. Once internalized iron may be transported to plasma or may be stored inside intestinal cells. There is flow of iron from intestine continuously to tranferrin and from there to ferritin then to erythrocytes. Finally from erythrocytes to monocytes – macrophage system back to tranferrin and ferritin[11].

Figure1- Absorption of iron



Ferritin is the storage form of iron which stores as many as 4500 atoms of iron. Mostly it is found in hepatocytes and macrophages. Apoferritin is hollow protein shell without iron core[11].

Specialized macrophages in bone marrow, liver, spleen recognize and phagocytise the old RBCs leading to liberation of haemoglobin, which gets catabolised to heme. Heme further metabolizes to biliverdin pigment and iron is released and then gets incorporated into ferritin or transports back to plasma[11].

Causes of Iron deficiency[10]

1. Increased requirement for iron
    a. Rapid growth in infancy or adolescent
    b. Pregnancy and lactation
    c. Erythropoietin therapy
2. Increased iron loss
    a. Chronic blood loss
    b. Menstruation
    c. Acute blood loss
    d. Blood donation
    e. Phlebotomy
3. Decreased iron intake, absorption or uses
    a. Inadequate diet
    b. Malabsorption due to disease or surgery
    c. Acute or chronic inflammation

Stages of iron deficiency[10]

Iron deficiency anaemia has a clear evidence of iron deficiency. It occurs in 3 different stages. The first stage is negative iron balance where the requirement for iron exceeds the body's capacity to absorb iron from diet. Causes for this may be numerous physiological

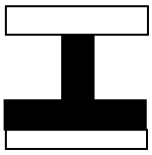
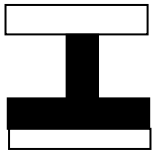
mechanisms like blood loss in menstruation, pregnancy, growth spurt in adolescents. Most commonly the growing needs of the foetus or adolescent exceeds the individual ability to absorb the total iron necessary for haemoglobin synthesis. Blood loss if more than 10-20 ml per day then it exceeds the amount of iron absorbed from a normal diet. This stage is recovered by mobilisation of iron from RES sites. In this stage iron majors like serum ferritin or the appearance of stainable iron on bone marrow aspiration depletes. So long as iron stores are not exhausted and can be mobilised the serum iron, TIBC and red cells protoporphyrin remains within the normal range. Red cell morphology and indices are normal[10].

As the iron supplies also deplete further, the serum iron starts to fall as well. Slowly the TIBC increases. There comes a stage when marrow iron reserve is also absent when serum ferritin level goes below 15µg/L. So far the serum iron is normal; haemoglobin synthesis is unaffected despite the decreasing iron stores. When the transferrin saturation falls below 15 to 20% haemoglobin synthesis becomes impaired. This stage is called iron deficient erythropoiesis. A careful observation of peripheral blood smear reveals the first appearance of microcytic cells, as well as hypo chromic reticulocytes in circulation. Gradually, haemoglobin and hematocrit starts falling, causing iron deficiency anaemia. The transferrin saturation is around 10-15%[10].

With moderate anaemia the bone marrow is hypo proliferative. In severe anaemia

(Haemoglobin 7- 8 g/dl), hypochromia and microcytosis becomes prominent, blood cells become poikilocytic and dismorphic and bone marrow becomes ineffective. With severe iron deficiency, hyperplasia of erythrocytes develops rather than hypoplasia[10].

Table2-Stages of iron deficiency[10]

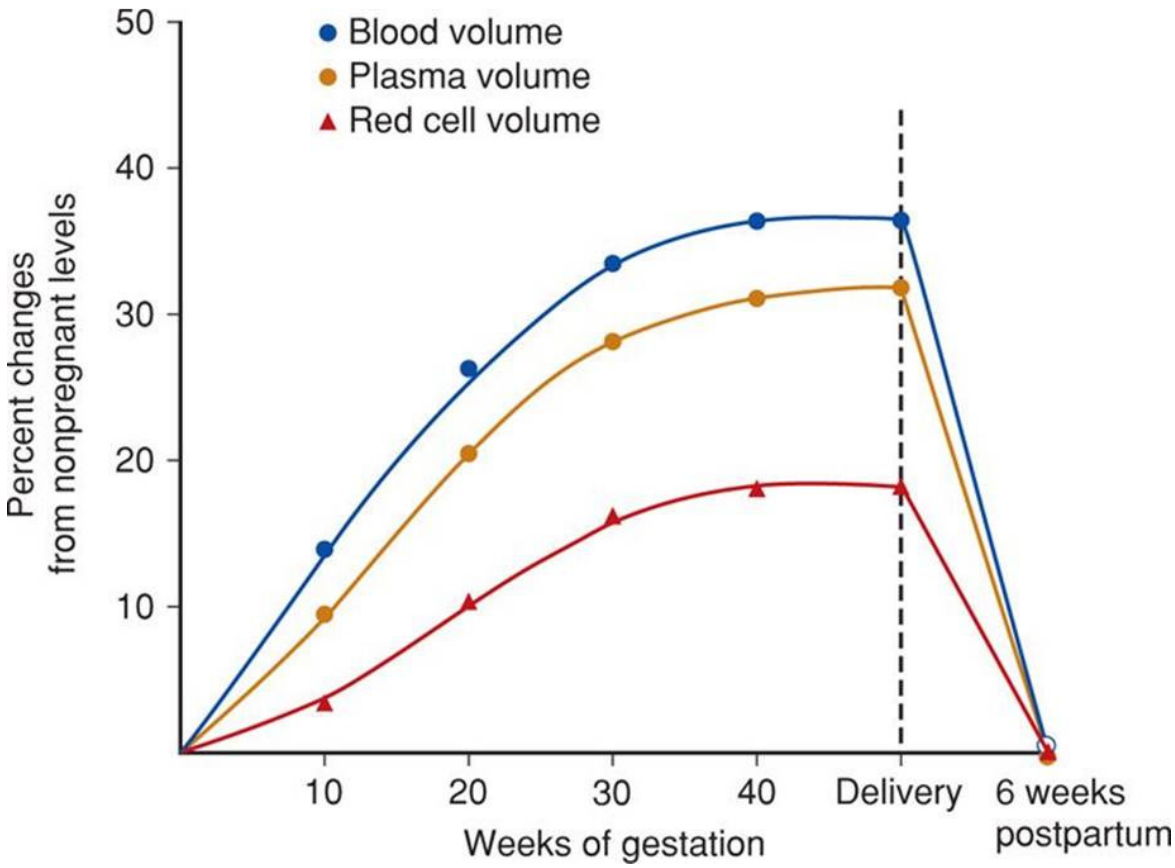
	Normal	Negative Iron Balance	Iron Deficient Erythropoietin	Iron Deficiency Anemia
Iron store Erythron Iron				
Marrow Iron stores	1-3+	0-1+	0	0
Serum ferritin (ug/l)	50-200	<20	<15	<15
TIBC (µg/dl)	300-360	>360	>380	>400
Serum Iron ((µg/dl)	50-150	normal limit	<50	<30
Saturation (%)	30-50	normal limit	<20	<10
RBC Morphology	normal limit	normal limit	normal limit	Microcytic hypochromic

HEMATOLOGICAL CHANGES IN PREGNANCY

BLOOD VOLUME:

Blood volume in pregnancy increases significantly. In non anaemic pregnant women blood volume at or near term is 40-50% above the non pregnant state. This expansion of blood volume differs in different women. Some have mild increase and in some volume doubles. In fact by 12 weeks the plasma volume expands by 15% of pre pregnant state. 2nd trimester volume expansion is maximum but in 3rd trimester this expansion is comparatively slower and platue in last several weeks[12].

Figure 2 – Haematological changes according to gestational age



Blood volume expansion occurs due to increase in both plasma and erythrocytes. Though plasma is more as compared to erythrocytes in maternal circulation, the increase in erythrocytes is around 450ml which is significant[13]. Moderate erythroid hyperplasia is present in bone marrow, and the reticulocyte count is elevated slightly during pregnancy. This corresponds to the increase in erythropoietin levels, which peaks in early 3rd trimester[14,15].

HEMOGLOBIN CONCENTRATION AND HEMATOCRIT:

Even though there is augmented erythropoiesis, haemoglobin concentration as well as hematocrit slightly decreases during pregnancy. Hence whole blood viscosity also decrease[16]. Haemoglobin concentration in an average is 12.5 g/dl near term and in around 6% pregnant women it is below 11g/dl[17].

IRON METABOLISM DURING PREGNANCY

IRON STORES:

The overall iron content of normal adult female is between 2.0- 2.3 which is half the amount of normal male. But iron stores of normal young are only about 300mg[10]

(Table-1).

IRON REQUIREMENTS:

Total requirements of iron during pregnancy differ with the body weight of the mother and the size and maturity of the foetus. In an average, demands for iron in pregnancy come to a total of about 900 mg (700-1400 mg)[9]. Uterus and its contents-500 to 600; Blood loss at delivery -150 to 200 mg ; Red cells mass expansion -500mg; Average saving due to amenorrhea -225 mg; Iron deficit -600 to 700mg. Requirements are 4mg/day approximately (2.5 mg/day in early pregnancy, 5.5 mg/day in 20-32 week/ 6-8 mg/day from 32 weeks onwards). As absorption is around 10%, for as little as of 4-6 mg absorption, 40-60 mg of iron should be available in the diet[9].

BLOOD LOSS:

In normal vaginal delivery as well as in caesarean delivery and in subsequent days after delivery only half of the erythrocytes added to maternal circulation are lost in the form of placental implantation site bleeding, episiotomy, surgical site and lochia. In an average, an amount of maternal erythrocytes corresponding to about 500ml to 600ml of pre-delivery blood is lost during and after vaginal delivery of a single fetus[18,19]. The average blood loss with caesarean is 1000ml same as twin vaginal delivery [18].

THE PROBLEM AND PREVALENCE OF ANEMIA

Anaemia is the most prevalent nutritional deficiency affecting pregnant females. Iron deficiency is the primary reason for anaemia followed by folic acid deficiency. The prevalence varies worldwide in different socio economic conditions, life style and health seeking behaviour. Anaemia affects 52% of developing nation's pregnant women as compared to 23% of developed nations[20].

Prevalence is higher in India as compared to other developing countries. Prevalence is highest in South Asian countries. According to WHO among Southern Asian countries India has highest prevalence. India contributes to 80% of the burden of maternal deaths due to anaemia. Anaemia is a major concern for perinatal morbidity and mortality as well[20].

According to NFHS survey 2005-2006 incidence of anaemia in pregnant women in India is 54.6% in urban areas and 59% in rural areas[20].

The functional outcome of iron deficiency in women of child bearing age group is well documented in literature.

PHYSICAL WORK PERFORMANCE:

Iron is obligatory for oxidative energy production. All levels of iron shortage adversely affect tissue oxidative capacity as well as oxygen carrying capacity[21]. So controlled trails have shown that iron deficiency with or without anaemia weakens aerobic fitness[22] as well as endurance capacity[21].

COGNITIVE FUNCTION AND MOOD:

Many researches in relation to iron deficiency and cognitive function have been done with strong evidence showing iron deficient individuals have poor cognition[23].

A study of pregnant teens at <16weeks gestation showed that twice daily 90grams of iron treatment for 4 weeks significantly improved attention span and memory[24].

Observations show association between maternal anaemia and depression as well. Iron deficiency devoid of anaemia also is related to depression and irritability[25].

IMMUNE FUNCTION:

Iron deficiency causes depression of immune function leading to amplified vulnerability to infections[26].

PREVENTION OF IRON DEFICIENCYPREVENTION IN NON-PREGNANT WOMEN

Girls in low resource countries like India are deprived of balanced diet since childhood and thus enter adulthood with malnutrition, anemia or low iron stores. As majority of women start their pregnancy with anemia, hence prevention should start even before pregnancy. As a community health advance, extended oral iron supply beginning prior to the woman happen to get pregnant may be a superior strategy to promote health the majority of the population[27]. Women of child bearing age in non-industrialized countries should receive a 2-4 month's course of 60 mg of iron daily[28].In April, 2008, the '12 by 12 initiatives' was introduced by the Government of India in collaboration with WHO, UNICEF and FOGSI. The goals of these initiatives are:

- To decrease the occurrence of anemia in adolescents to ensure healthy parenthood.
- To increase awareness among adolescents regarding anemia and appropriate nutrition.

The program waslaunched through school scheme, where iron supplementation through weekly iron tablets is given to school children[29].Routine iron supply should be given to all women who are pregnant in low resources countries[30,31]. The Government of India initiated the National Nutritional Anemia Prophylaxis Program(NNAPP) in 1970 to provide iron plus folic acid supplements to pregnant women, lactating women, family planning acceptor women and children aged 1-11 years old[32].

PREVENTION OF IRON DEFICIENCY IN PREGNANCY

UNIVERSAL SUPPLEMENTATION

Two groups, the **International Nutritional Anemia Consultative Group (INACG)** and the World Health Organization (WHO) recommend universal supplementation with 60 mg/d of elemental iron, from booking, or from the second trimester[33].This approach was first provided by **Mother Care Project** in 1993, who reviewed the results of 24 well conducted world-wide trials[34]. All studies resulted in a positive effect of supplementation on maternal iron status. The **Cochrane database** established these made results, reviewing around 49 trials which included 23,200 pregnant women. Even though heterogeneity made results tricky to quantify between the studies, relative risk-reduction of anemia at term was 30-50% for those receiving daily iron supplement with or without folic acid[35, 36].

However the studies reviewed in the Cochrane database is insufficient to draw conclusions about the impact on maternal and fetal outcomes and randomized controlled studies have found conflicting evidence that maternal or neonatal physical wellbeing will improve from correcting these deficits[37,38].

PRACTICAL DIFFICULTIES

There are clear logistical problems associated with widespread use. These include cost and supply of iron tablets and cost and ability to deliver adequate supportive care[39].

MANAGEMENT OF IRON DEFICIENCY ANAEMIA

Along with volume replacement, treatment options include the administration of oral iron, parenteral iron and heretologus (donor) blood. Another option to be considered is the administration of recombinant erythropoietin (rhEPO)[40].

The severity and reason for iron deficiency anemia will decide the suitable approach to management. For instance, indicative patients with severe iron deficiency anemia and cardiovascular volatility may require red cell transfusions. Patients who have compensated for their anemia can be treated more predictably with iron replacement[10].

For the majority of cases of iron deficiency, oral iron therapy will suffice. For patients with unusual blood loss or mal-absorption, specific diagnostic tests and appropriate therapy take priority. Once the finding of iron deficiency anemia and its cause is made, and a therapeutic approach is planned, there are three major approaches-donor blood transfusion, oral iron therapy and parenteral iron therapy[10].

DONOR BLOOD TRANSFUSIONS

Transfusion therapy is reserved for those individuals who have symptoms of anemia, cardiovascular instability, and continued and excessive blood loss, from whatever source, and those who require immediate intervention. Not only do transfusions rectify the anemia acutely, but the transfused red cells offer a source of iron for reutilization, assuming they are not lost through unrelenting bleeding. Transfusion therapy will alleviate the patient while other alternatives are reviewed[10].

Situations that can lead to a donor blood transfusion [40]

- Postpartum anemia with signs of shock.
- Severe acute blood loss following spontaneous delivery or caesarean section

ORAL IRON THERAPY

In the patients with established iron deficiency anemia who are asymptomatic, therapy with oral iron is usually sufficient[10].

Typically, for iron replacement therapy, up to 300mg of elemental iron per day is given, usually as three or four iron tablets (each containing 50 to 65 mg elemental iron) given over a day. The goal of therapy in individuals with iron deficiency anemia is not only to repair the anemia, but also to provide stores of at least 0.5 to 1 g of iron. Sustained treatment for duration of 6 to 12 months after correction of the anemia will be necessary to achieve this[10].

Of the complications of oral iron, gastrointestinal stress is the most prominent and is seen in 15 to 20% of patients. For these patients, abdominal pain, nausea, vomiting or constipation often

leads to noncompliance. The gastrointestinal complications are a major barrier to the effective treatment of a many patients[10].

Multiple preparations are available ranging from simple iron salts to complex iron compounds, designed for sustained release throughout the small intestine[28].

PARENTERAL IRON THERAPY

Parenteral iron is the most important alternative to oral iron preparations.

The therapy is given when there is total non-cooperation with, or intolerance to, oral iron or proven malabsorption[41].

It may be given to patients who are[42]:

1) Unwilling to take iron by oral route,
2) Unable to tolerate oral iron (e.g., patients with peptic ulcer, regional ileitis or ulcerative colitis),
3) Unable to absorb iron well (e.g. spruce),
4) To patients who loose relatively large amounts of blood from gastrointestinal lesions that are not amenable to surgical treatment (e.g. congenital telangiectasia, inoperable cancer and blood loss of obscure origin).
5) Insufficient response to oral iron
6) Severe anemia
7) The need for rapid efficacy
8) Combination with recombinant human erythropoietin (rhEPO) (for prevention of functional iron deficiency)

Intramuscular iron therapy is to be discouraged because of its adverse effect which includes pain, irregular absorption and staining[42].

The intravenous route has some advantage over intramuscular injection in

a) Bedridden, immobilized patients who have greatly reduced lymph flow and less absorption of iron dextran from the muscle depot,

b) Patients without much muscle mass,

c) Patients requiring multiple, relatively large injections of iron who find that intra muscular administration causes discomfort, and

d) Patients with severe blood loss from idiopathic thrombocytopenic purpura who might have tissue bleeding after intramuscular injections.

The high plasma iron concentrations that occur shortly after I.V. administration bypass the limited release of iron from the reticulo-endothelial system and inhibit absorption through the intestinal mucosa thus delivering sufficient quantities of iron for erythropoiesis[40].

Various regimens of supplementation of iron during pregnancy are followed worldwide including daily and intermittent supplementation. In India we widely use daily supplementation which is largely ineffective for a variety of reasons most important being insufficient supply and poor compliance due to various side effects of intake of elemental iron.

Institute of Medicine[43, 44,45] (1990) Iron deficiency is extensive amongst women who are pregnant in industrialized countries, confirmed by many studies in which hemoglobin concentrations during the last half of pregnancy were found to be elevated in iron-supplemented women than in those given a placebo or no supplement. This elevated hemoglobin concentration as a consequence of a better iron supply not only improves the oxygen-carrying ability, but it also offers a buffer against the blood loss that will occur during parturition.

A study conducted by **Endi Ridwan E et al [46](1996)** The effect of weekly iron supplements in expectant women in Indonesia women were compared to that of daily supplementation. One subgroup had 68 women and other had 71 women. First group

received 60mg of elemental iron daily and second group received 120 mg of weekly. The study concluded that there was no significant difference between groups for changes in hemoglobin but serum ferritin levels did not show any significant concentration.

International Anemia Consultative Group (INAG)/WHO/UNICEF had published the most current international guidelines for use of iron supplements.

- *Pregnant women in areas with anemia prevalence <40%*: One tablet containing 60mg elemental iron plus 400 µg folic acid for 6 months during pregnancy. If a 6 months duration cannot be achieved in pregnancy, one tablet is continued for 6 months postpartum or doseincreasedto120mg.
- *Pregnant women in areas with anemia prevalence >40%:*One tablet containing 60mg elemental iron plus 400µg folic acid for 6 months during pregnancy and 3 months postpartum.
- Recent investigations have suggested that elemental iron in dosage as low as 60 mg twice weekly is beneficial in selected populations.

While medicinal iron supplementation to selected groups at risk is important, the need to augment ingestion of iron must be recognized as this is the obvious logical approach. Further research is required for determining optimal dosage schedule of iron replacement therapy.

According to **INACG, Rebecca J. Stoltzfuset al[47](1998)** the dosage for iron supplementation in mass program is unchanged from previous recommendations except, that the pregnancy dose has been reduced to 60mg/day.

Because the efficiency of absorption of iron increases as iron deficiency anemia becomes more severe, this dose should provide adequate supplementation to women who do not have clinically severe anemia, if it is given for an adequate duration.

However, if the duration of supplementing iron during pregnancy is short, a higher dose (120mg / day) is recommended.

Supplementation, involves the administration of iron salts to those individuals, whose physiological needs are greatest.

Relatively small supplements of 20-30mg daily taken between meals are required to prevent iron deficiency.

According to **National Consultations on Control of Nutritional Anemia in India[48] (1999) –** one tablet which contains100mg elemental iron and 500mg folic acid to be taken daily. A minimum of 100 such tablets are to be consumed in pregnancy during second and third trimester.

Ameet Patki et al[49] (2000) carried out a randomized prospective double blind trial to study low dose iron versus high dose iron preparations in pregnancy. A total of 60 pregnant women with in the gestational age of 20 to 34 weeks with hemoglobin percentage in the range of 8-11gm, presenting in the antenatal clinic were selected. They were randomly selected to either of two groups, one containing a low dose iron preparation (30 mg of elemental iron) and the other group containing a high dose preparation (100mgof elemental iron). Both the doctors and the patients participating in the trial knew anything about the preparation of the tablets used in the trial. All patients were counseled about the trial and were asked to consent for the same. Comparison was done in terms of the changes in the hemoglobin during the duration of the pregnancy, the maternal weight gain and changes in the systolic and diastolic blood pressure, baby weight at birth, patient compliance and adverse events if any. The study showed there was no statistically significant difference in the two groups related to maternal weight gain or difference in the systolic and diastolic blood pressure. On the other hand there was a significant statistical rise in the hemoglobin level in the group given the low dose iron preparation. Also the baby weight at birth

was more in the same group. This was probably due to the decreased rate of adverse events experienced by the patients and hence an increased compliance for treatment. It was thus concluded that a low dose preparation is enough to maintain the pregnancy requirements and also leads to enhanced patient tolerance and improves patient compliance.

Thomas H Bothwell et al[9](2000) concluded that knowing the iron status during pregnancy is laden with problems because the intense hemodynamic changes related to pregnancy concern several indexes of iron status. In pregnancy, hemodilution causes reduced haemoglobin concentration, while both serum iron and ferritin concentrations reduce and total iron-binding capacity gets enhanced. The relative contributions of pregnancy per se and a pregnancy-related negative iron balance causing these changes can be assessed by the changes in haemoglobin, serum iron, serum ferritin and total iron-binding capacity which happens in pregnancy in women provided adequate iron supplementation during pregnancy has been given to overcome these changes.

Mumtaz Z et al[50](2000)studied the results of twice weekly iron supplement compared to daily in Pakistan. It was a double-blind, randomized, clinical trial. Anaemic pregnant women were to receive daily (200 mg ferrous sulphate) or twice weekly (2 x 200 mg ferrous sulphate) iron supplementation. Haemoglobin was measured at first visit and at 4-wk intervals for up to 12 wk. Serum ferritin was calculated at first visit as well and 8 or 12 wk respectively. Results were obtained with the intention to treat. The two groups did not differ in socio demographic characteristics, haemoglobin or serum ferritin concentrations. Women who were given iron daily had a more rise in haemoglobin compared to women who received iron twice weekly. The serum ferritin concentrations also rose in the daily supplemented group and did not change in the twice weekly group. Daily iron supplementation was superior to twice weekly supplements.

John L Beard et al[51] (2000) showed that giving daily iron protects a reducing storage status of pregnant women rather than giving intermittently.

Kiran Coelho et al[52](2001) conducted in a study taking 100 pregnant women with gestations between 20 and 34 weeks and hemoglobin between 7-12 gm%. They did the study in the clinic at the Bandra Holy Family Hospital, Bandra, Mumbai. Patients were assigned to either of the two groups. The Trial group was given a low dose iron preparation (30mg elemental iron). The Control group was given a high dose iron preparation (116 mg elemental iron). Study was carried out to see the hemoglobin levels, the maternal weight gain, effective fetal weight, side effects, complications, and compliance of the patients. They concluded that 30mg of elemental iron is sufficient to maintain iron in pregnancy and also leads to better tolerance and improved compliance. In mild anemia, or in pregnancy, to prevent iron deficiency, 15-30mg elemental iron is sufficient for daily requirement, even though taken with food. The oral iron many a times causes gastrointestinal irritation and abdominal pain with nausea, vomiting, diarrhea or constipation. These side effects are due to the amount of elemental iron rather than the type of preparation.

Shatrugna V et al[53] (2001) randomly allotted pregnant to receive different formulations then to undergo iron tolerance test, the data showed that increasing the dose of elemental iron from 60-180mg improved the bioavailability, but was related to many undesirable side effects. The results showed that 60mg of elemental iron is best tolerated.

Ekström et al[54](2002) concluded that iron absorption with weekly iron supplements is not higher than that with daily supplements. However, many community-based trials have repeatedly shown that a weekly regimen is as effective as a daily one. Moreover when differences in absorption are found, they are commonly negligible than would be expected on the basis of differences in the amount of iron provided.

Jemal H et al[55] (2003)demonstrated the effectiveness and social feasibility of weekly versus daily iron supplementation in preventing and treating iron deficiency anaemia among anaemic mothers in Addis Ababa, Ethiopia. The daily supplemented group took 60 mg of elemental iron and 400 µg folic acid. The weekly group received one tablet once a week. Weekly group was

supervised while the control group was advised to take no medications without the knowledge of the investigators during study period. They concluded weekly supplementation is simple, comparable to daily supplementation and economically better. Thus, it was recommended to adopt in controlling anaemia. Further because of higher compliance rate and lower side effects, it was told to be socially feasible.

Charles Vega et al[56](2003) concluded that supplementing the diet of women with 20mg iron per day from week 20 of pregnancy until delivery was an effective strategy for preventing IDA and ID without side effects. Also told high-dose iron supplements, causes many undesired side effects.

J. Haidar A.M. et al[57](2003)showed the effectiveness and social feasibility of weekly versus daily iron supplementation in preventing and treating iron deficiency anemia in anemic mothers. They told that Weekly supplementation is simple, comparable to daily supplementation and economically better. Hence recommended it to adopt the strategy control of anemia. Further because of higher compliance rate and lower side effects, it was thought to be socially feasible.

Siddiqui IA et al[58] (2004) undertook study to compare the results of once-weekly vs. daily oral iron supplementation in schoolchildren and concluded that once-weekly iron supplementation is as effective as daily supplementation for the treatment of iron deficiency anemia. Moreover, weekly iron supplements are cost effective and have no or fewer side-effects.

Ahmadreza Z et al[59] (2008) studied pregnant women in two different clinics in Isfahan, Iran. The inclusion criteria were 2nd trimester pregnant women aged between 18-38 years with the initial Haemoglobin>= 110 g/L. They were assigned to two treatment groups, either the twice weekly taking iron group (two 45-mg ferrous tablets per week) or daily taking iron group (45 mg ferrous table) &told Daily regimen was more effective than twice weekly regimen in preventing anaemia near term.

A study conducted by **Esther Casneva et al[60] (2010)** by taking women with singleton pregnancies and blood hemoglobin>115gm/l at gestational age 20 weeks were put to two groups one consuming one tablet of 60mg elemental iron and other consuming two tablets once weekly. Hemoglobin and serum ferritin concentration were measured every week from weeks 20 to 36 and pregnancy and results were evaluated. The study concluded that in women who were non anemic for them both schedules prevent the occurrence of hemoglobin level<10mg/dl. In daily supplementation group women had a higher incidence of hemo concentration and it was associated with increased risk of low birth weight and premature delivery.

Under the **National CSSM programme[61] (2010),** Ministry of Health and Family Welfare, Govt. of India has recommended 2 tablets of iron and folic acid each containing 100mg elemental iron and 500mg folic acid to all women who have Hb <11g%.They advised deworming course with 6 tablets of mebendazole (100 mg) in second and third trimester of pregnancy (1bdx 3 days) in areas with high prevalence of hook worm infestation as well.

Bouzari Z et al[62] (2011) studied & did comparisons of iron supplementation in three time frames- daily, weekly and three time weekly supplementation in preventing anaemia in healthy pregnant women. And there were no significant differences between the pre- and post-treatment haemoglobin levels with iron supplementation in all the groups. This result suggested, three times a week or weekly iron supplementation is as effective as daily supplementation for healthy pregnant women without anaemia.

WHO guidelines[6] (2012) says Intermittent iron and folic acid supplementation is recommended in non-anaemic pregnant women to prevent anaemia development and to improve gestational outcomes (strong recommendation). The quality of the evidence for low birth weight, birth weight, premature birth, maternal anaemia at term, iron deficiency anaemia at term, and side-effects was very low.

A **Cochrane data base systemic review[63] (2012)** advised intermittent oral iron supplementation during pregnancy. Review included 21 trials from 13 different countries with in total 4072 women. It concluded that intermittent iron and folic acid regimen produced similar maternal and infant outcomes at birth but with a fewer side effects hence should be followed as an alternative.

Sarah Hanieh et al[64] (2013)told Daily supplementation of iron tablets to pregnant women does not provide any benefits in terms of birth weight or improved infant growth compared to twice weekly supplementation.

Arija V et al[65] (2013) described the prevalence of iron depletion (ID), iron-deficiency anemia (IDA) and risk of hemo-concentration during pregnancy and at delivery and to assess the influence of initial Fe stores and Fe supplementation on that prevalence. They concluded that the prevalence of ID and IDA was high in late pregnancy in healthy pregnant women, particularly in those with initial ID and/or those not taking supplements. Starting pregnancy with no ID and/or taking moderate Fe supplementation decreased the likelihood of ID at delivery. The risk of hemo-concentration was high at delivery, but did not seem to be promoted by iron supplementation. It is necessary to determine the most appropriate nutritional advice for pregnant women as well as dosing of iron though it s proved iron is required apart from dietary intake.

Hawamdeh HM et al[66] (2013) studied the efficacy of daily versus twice weekly and once weekly oral iron therapy and analyzed to optimize a protocol for treatment of IDA among Jordanian children. They showed that the regimen of two doses per week is the most effective in resolving anaemia with less cost and fewer side effects.

Bagchi et al[2](2015) Compared effectiveness of weekly supplementation of 200 mg elemental iron with daily supplementation of 100mg elemental iron on iron indices along with hemoglobin and hematocrit values in pregnant women. They concluded that the weekly supplements to pregnant women had desired effect on iron indices except for the serum ferritin level which can be overcome by extending the supplementation to the post-partum period.

Peña-Rosas JP et al[3] (2015) told that intermittent oral iron and folic acid supplementation with 120mg of elemental iron and 2800µg (2.8 mg) folic acid once weekly is recommended for pregnant women to improve maternal and neonatal outcomes if daily iron cannot be given due to undesirable side-effects, and in populations with an anemia prevalence among pregnant women of less than 20%. The equivalent of 120mg of elemental iron is 600mg ferrous sulfate heptahydrate, 360 mg ferrous fumarate or 1000 mg ferrous gluconate.

Food and nutrition board of institute of Medicine[67] (2016) – Recommends routine use of daily iron supplements (30mg/d) after 12th week of gestation in along with a well-balanced diet.

Siabani S et al[5] (2018)assessed the compliance with iron and folic acid supplementation, and the causally associated factors, among pregnant women in western Iran. They concluded that, most women had not started taking the supplements regularly or at the correct time, usually due to forgetting and/or experiencing unpleasant side-effects.

Rajoria L et al[1] (2018) concluded that prophylactic oral iron supplements when given intermittently were not as effective in preventing iron deficiency anemia in pregnancy as daily iron was. In non-anemic pregnant women, a weekly regimen is an effective alternative to a daily regimen for antenatal oral iron and folic acid supplements for preventing anemia and iron deficiency during the third trimester.

Tandon R et al[7] (2018) Indicated for knowing serum ferritin levels in pregnancy; (a) prior to starting iron therapy in patients to know hemoglobinopathies. (b) When a different cause of microcytic anaemia is being considered like chronic inflammation, lead toxicity, sideroblastic anaemia etc.(c) Suboptimal response to oral iron when compliance is doubtful(d)In non anaemic women at higher risk of iron deficiency. (e)After 8 weeks of therapeutic iron when non anaemic iron deficiency is being treated.(f)Preferably prior to any parenteral iron preparation.

Iglesias Vázquez L et al[4] (2019) conclude that the prenatal iron supplementation has a different effect on maternal iron status at the end of pregnancy according to initial levels of haemoglobin

and serum ferritin and could contribute to improving public health programmes and to adapting clinical settings to the population group at risk. They took many associated prenatal determinants for improved antenatal care. It is important to have full iron reserves before pregnancy and to consider high cost of iron during pregnancy id patients land up in anaemia; and secondly, they recommended for iron supplementation for maintenance of haemoglobin and iron reserves to pre pregnant states.

Loy S.L et al[68](2019) used multiple biomarkers to measure iron status and found serum ferritin was the most relevant in pregnancy and proposed it as the most sensitive single screening test for iron stores. According to the World Health Organization [WHO], plasma ferritin levels of lower than 15μg/L indicate iron depletion (loss of iron stores) at all stages of pregnancy. This threshold also confirms the presence of iron deficiency anemia. But the range of low ferritin varies in different settings.

Muhammad Rizki Yaznil1 et al[69] **(2019)** compared the clinical side effects between pregnant women with daily and weekly iron supplementation. And concluded that the daily iron supplements increase the episodes of nausea and constipation during pregnancy than the weekly supplements and severely decreases the compliance.

Kumar Agrawal et al[70] **(2020)** took 141 healthy pregnant women without anemia, which were between 14 - 20 weeks of pregnancy and allocated them into two equal groups randomly. The first group (n = 55) received a 100 mg-ferrous sulphate tablet daily, the second group (n = 55) received a 100 mg-ferrous sulphate tablet two tablets once weekly, respectively till delivery. Serum haemoglobin, ferritin, and iron were measured before and after the supplements. They told that there were no significant differences between the pre- and post-treatment haemoglobin levels and serum ferritin levels with iron supplementation in the two groups when the maternal haemoglobin level was >11g/dL before the study. But for those who had a haemoglobin concentration <11gm/dL at the starting of the study, the rise in haemoglobin concentration was

significantly greater at the end in the daily supplemented group as compared to the weekly group.

According to **American College of obstetrics and Gynecology[71](2021)** – 30mgof elemental iron per day insufficient, but if the woman has multiple pregnancy or later on pregnancy then higher dose of 60-100mg of elemental iron should be given.

Magdy Abdelgawad et al[72] (2021) aimed to compare the hemoglobin levels in non anemic pregnant women receiving weekly versus daily iron supplements. There could not be any difference which could be detected between both groups as regards the demographic data, body mass index, interval since last pregnancy, hemoglobin level before starting iron supplementation and duration of supplementation.

Form all this it was concluded that intermittent regimens produced similar maternal and infant outcomes as daily supplementation and was associated with fewer side effects and also decrease the risk of high levels of hemoglobin in mid and late pregnancy, although the risk of mild anemia near term was increased. While the quality of the evidence was assessed as low or very low, intermittent regimen for iron ingestion might be a feasible alternative to daily iron supplementation among those pregnant women who are not anemic and have received adequate antenatal care.

METHODS AND MATERIAL

STUDY DESIGN: Prospective Cohort Study.

PLACE OF STUDY: Department of Obstetrics & Gynecology, Santosh Medical College Hospital, Ghaziabad, Uttar Pradesh, India.

STUDY POPULATION: All Pregnant women with gestational age between 12-28weeks reporting to Obstetrics OPD.

DURATION OF STUDY: One year study from July 2021 to June 2022.

SAMPLE SIZE: Sample size was calculated taking the prevalence of anemia to be 73% and formula as below:

$$N=\frac{z^2.\ p(1-P)}{D^2}$$

Z= 1.96

P= prevalence

D= precision

Required sample size n = 71.6

Sample size came out to be 71.6 rounded up to 80

Approval was obtained from the ethical committee of Santosh University.

Informed consent was taken from all subjects.

INCLUSION CRITERIA:

1) Pregnant women (primigravida or multigravida) with gestational age 12-28wks.

2) Hemoglobin level 10mg/dl or more.

3) Corrected hemoglobin of pregnant women having less than 10mg/dl hemoglobin level before correction.

4) Singleton pregnancy.

EXCLUSION CRITERIA:

1) Pregnant women with gestational age less than 12 weeks and more than 28weeks

2) Pregnant patients with hemoglobin level less than 10mg/dl.

3) Patients having other causes of anemia like hemolytic, thalassemia, anemia due to infection, liver disease, renal disease etc.

4) Pregnancy with medical disorders like cardiac disorder, connective tissue disorder etc

5) Multiple gestations

METHODOLOGY:

This prospective study was conducted in Santosh Medical Hospital, Ghaziabad- 201001 (U.P).

FIRST VISIT: All women attending the outdoor unit with pregnancy between 12-28 weeks were offered the option of being included in this study. Those who agreed were asked to complete a questionnaire including demographic features, detailed obstetric and menstrual histories and pregnancy symptoms. Women with gestational age of 12weeks to 28 weeks with hemoglobin levels more than or equal to 10mg/dl & who fulfilled the inclusion and

exclusion criteria were recruited for the study randomly and divided into two groups. Total 126 women were recruited out of which 6 were lost to follow up and in final study 120 were taken and 60 in each group were randomly taken.

Group A –Pregnant women who were given daily 60mg of elemental iron.(420mg/week-high dose)

Group B -Pregnant women who were given weekly 120mg of elemental iron.

(120mg/week – low dose)

Iron tablets along with folic acids were provided as per the group.

Patients were given dietary advice. They were instructed to take iron after food and to avoid tea and coffee before iron intake. They were explained about the possible side effects and also were informed about subsequent visit.

SECOND VISIT: All patients were called after one month (4weeks). Detailed follow up was done in respect to patients' compliance and side effects of taking both regimens of oral iron. Hemoglobin was repeated to know the improvement.

If the hemoglobin levels were maintained at 10 gm/dl or above, then patients continued to take their respective regimens.

However, if there was any fall in hemoglobin level below 10 gm/dl in either group, then alternative methods to treat anemia were adopted (Daily regimen in patients of weekly dose, and higher dose/injectable iron in daily dose group)

Patients continued to take their respective regimens till rest of their pregnancy.

FINAL VISIT: Patients were assessed finally at the time of delivery with respect to hemoglobin level to know the effect of both the regimens.

STATISTICAL ANALYSIS:

The data were collected and tabulated. The observations were described in terms of percentages and proportions. Data were compiled and statistically analyzed using the Chi- square test, Student's t- test where applicable. $P < 0.05$ was considered statistically significant.

OBSERVATIONS & RESULTS

The study "**A comparative study of conventional daily versus low dose weekly oral iron supplementation in preventing anemia during pregnancy"** was conducted at Santosh Hospital Obstetrics and Gynecology Department between July 2021 to June 2022. In the study total 126 pregnant women were taken initially, out of which 6 were loss to follow and 120 were included in the final observation. Calculations were done using Chi-Square and Fisher's exact test and following observations were made:

TABLE 3- DISTRIBUTION OF PATIENTS ACCORDING TO AGE

AGE (yrs)	DAILY REGIMEN		WEEKLY REGIMEN		TOTAL		p VALUE
	n_1= 60	%	n_2= 60	%	n_1+n_2= 120	%	
≤ 20	5	8.33	6	10	11	9.17	0.157
21- 30	51	85	45	75	96	80	
>30	4	6.67	9	15	13	10.83	
TOTAL	60	100	60	100	120	100	
MEAN	26.03± 3.60		26.30±3.25				

In the present study, daily oral iron group had 5 (8.33%) pregnant women in the age group ≤ 20 years, 51 (85%) between age group 21- 30 years and 4 (6.67%) were 30 years and above. In the weekly oral iron group 6 (10%) were in the age group ≤ 20 years, 45 (75%) between age group 21- 30 years and 9 (15%) were 30 years and above. The mean age in daily oral iron group was 26.03± 3.60 and in weekly oral iron group was 26.30± 3.25 years. There was no statistical significance between the two groups. (**Table 3; Figure 3**)

FIGURE 3- DISTRIBUTION OF PATIENTS ACCORDING TO AGE

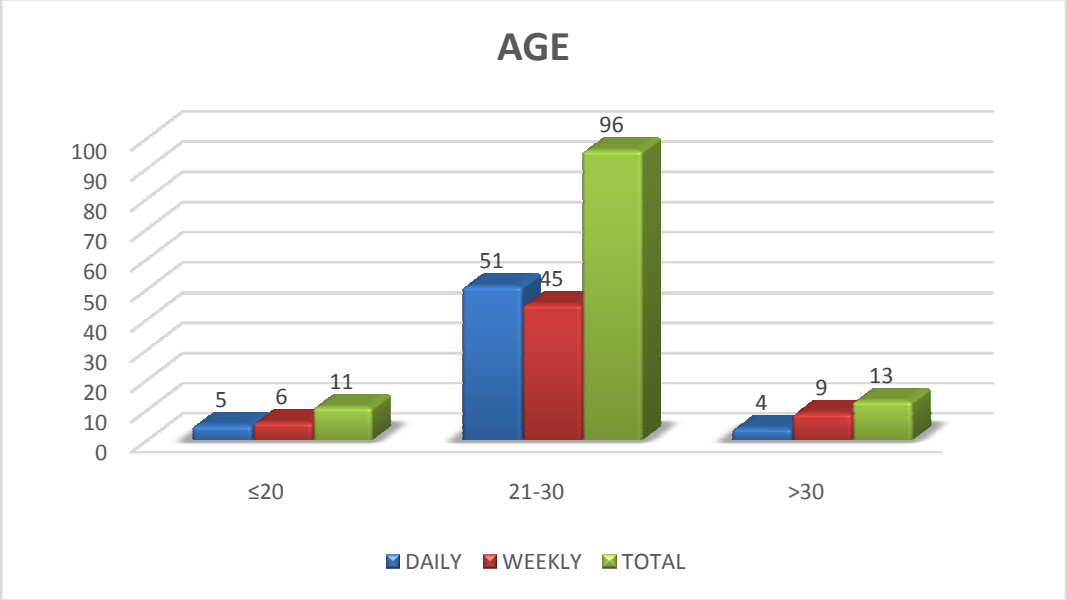


TABLE 4- DISTRIBUTION OF PATIENTS ACCORDING TO RELIGION

RELIGION	DAILY		WEEKLY		TOTAL	p value
	n_1=60	%	n_2=60	%	n_1+n_2 = 120	
HINDU	53	88.34	52	86.67	105	
MUSLIM	5	8.33	5	8.33	10	
OTHERS	2	3.33	3	5	5	0.157
TOTAL	60	100	60	100	120	

In the present study, in daily oral iron 53 (88.34%) were Hindu, 5 (8.33%) were Muslim and 2 (3.33%) were in others group. Similarly in weekly oral iron group 52 (86.67%) were Hindu, 5 (8.33%) and 3 (5%) were in other group. There is no statistical significance between the two groups. (**Table 4; Figure 4**)

FIGURE 4- DISTRIBUTION OF PATIENTS ACCORDING TO RELIGION

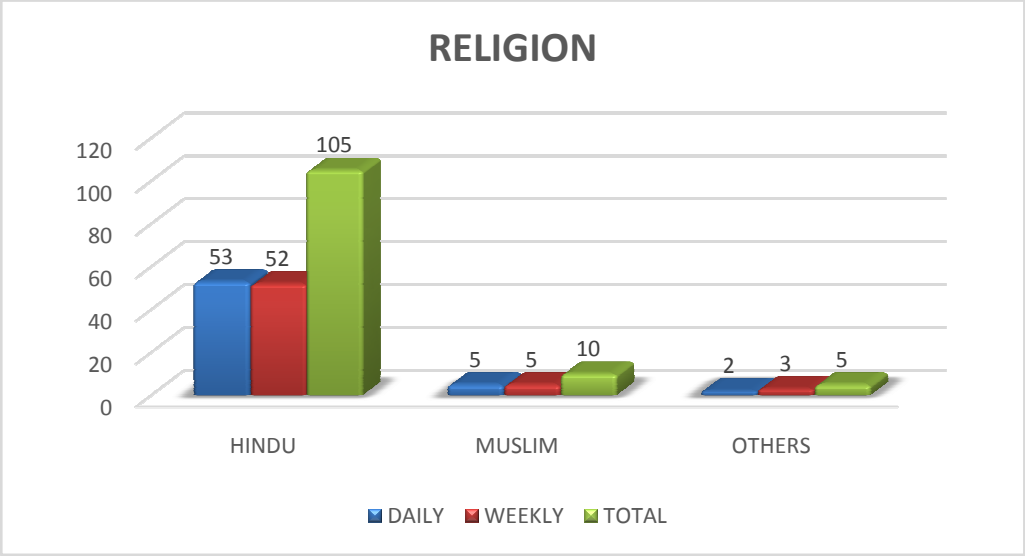


TABLE 5- DISTRIBUTION OF PATIENTS ACCORDING TO LOCALITY

LOCALITY	DAILY REGIMEN		WEEKLY REGIMEN		TOTAL	P VALUE
	n_1=60	%	n_2=60	%	n_1+n_2 = 120	
RURAL	32	53.33	31	51.67	63	1
URBAN	28	46.67	29	48.33	57	
TOTAL	60	100	60	100	120	

In the present study, the daily iron group had 32 (53.33%) pregnant women from rural area where as weekly group had 31(51.67%) pregnant from rural area. In daily urban group 28(46.67%) were there and 29(58.33%) belonged to weekly urban group. There was no statistical significance between the two groups. **(Table 5; Figure 5)**

FIGURE 5- DISTRIBUTION OF PATIENTS ACCORDING TO LOCALITY

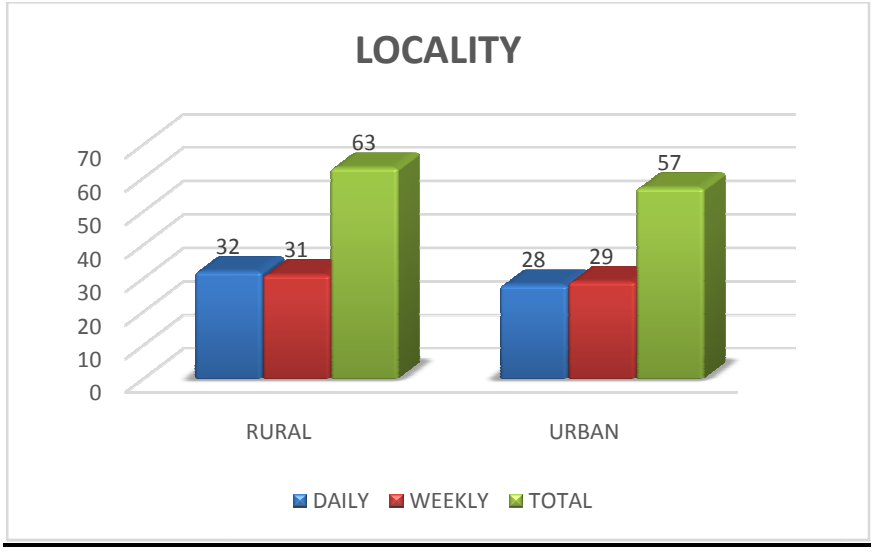


TABLE 6- DISTRIBUTION OF PATIENTS ACCORDING TO EDUCATION

Education	Daily regimen		Weekly regimen		Total	P value
	n_1=60	%	n_2=60	%	n_1+n_2 = 120	
ILLETERATE	28	46.67	25	41.67	53	0.157
PRIMARY SCHOOL	20	33.33	20	33.33	40	
MIDDLE SCHOOL	6	10	10	16.67	16	
HIGH SCHOOL	5	8.33	3	5	8	
GRADUATE	1	1.67	2	3.33	3	
TOTAL	60	100	60	100	120	

The distribution of patients on the basis of education in oral daily group was illiterate 46.67% , primary school 33.33%, middle school 10%, high school 8.33% and graduates 1.67%. In weekly group 41.67% illiterate, 33.33% primary school, 16.67% middle school, 5% high school and 3.33% graduates. There was no statistical significance between the groups. (**Table 6; Figure6**)

FIGURE 6- DISTRIBUTION OF PATIENTS ACCORDING TO EDUCATION

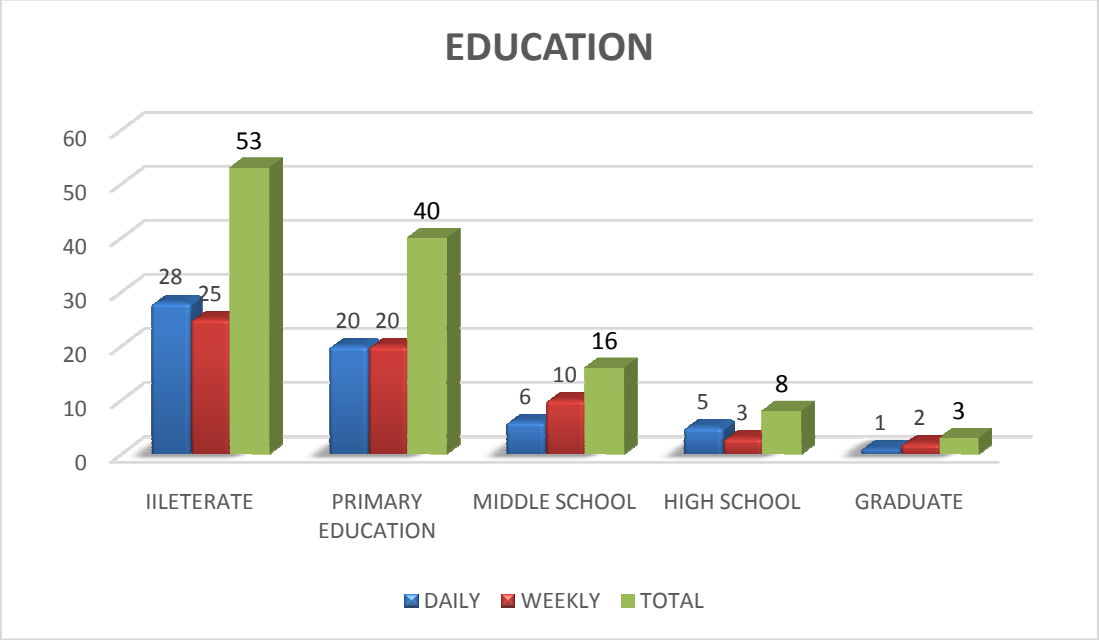


TABLE 7- DISTRIBUTION OF PATIENTS ACCORDING TO OCCUPATION

OCCUPATION	DAILY		WEEKLY		TOTAL		P VALUE
	n_1= 60	%	n_2= 60	%	n_1+n_2= 120	%	
HOUSEWIFE	51	85	53	88.33	104	86.67	
WORKING	9	15	7	11.67	16	13.33	0.789
TOTAL	60	100	60	100	120	100	

In the present study, in the daily group 51 (85%) pregnant were included in daily iron group who were housewives while 9 (15%) were working class. Similarly 53 (88.33%) were housewives in weekly iron group and 15 (11.67%) were working class. There was no statistical significance between the two groups. (**Table 7;Figure 7**)

FIGURE 7- DISTRIBUTION OF PATIENTS ACCORDING TO OCCUPATION

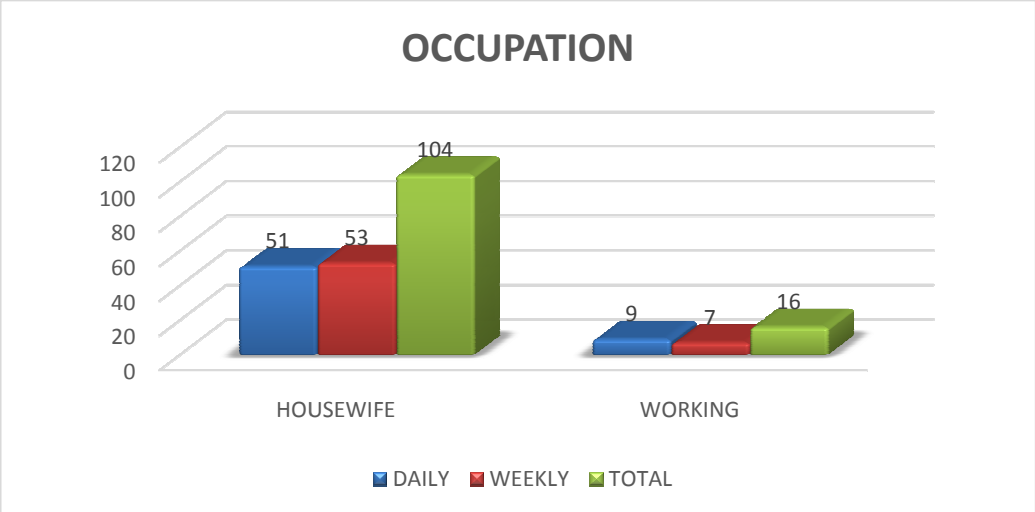


TABLE 8- DISTRIBUTION OF PATIENTS ACCORDING TO SOCIOECONOMIC STATUS

SOCIOECOMIC STATUS	DAILY REGIMEN		WEEKLY REGIMEN		TOTAL	P VALUE
	n_1=60	%	n_2=60	%	n_1+n_2= 120	
LOWER	31	51.67	26	43.33	57	
MIDDLE	23	38.33	25	41.67	48	
UPPER	6	10	9	15	15	0.464
TOTAL	60	100	60	100	120	

In the above study, both daily and weekly groups were divided in 3 groups like lower, middle and upper class. In daily group lower class had 31 (51.67%) pregnant women, middle class was having 23(38.33%) and upper class had 6 (10%) women. In weekly group lower class had 26 (43.33%) women, middle class had 25 (41.67) and upper class had 9 (15%) women. There was no statistical significance between two groups. (**Table 8; Figure8**)

FIGURE 8- DISTRIBUTION OF PATIENTS ACCORDING TO SOCIOECONOMIC STATUS

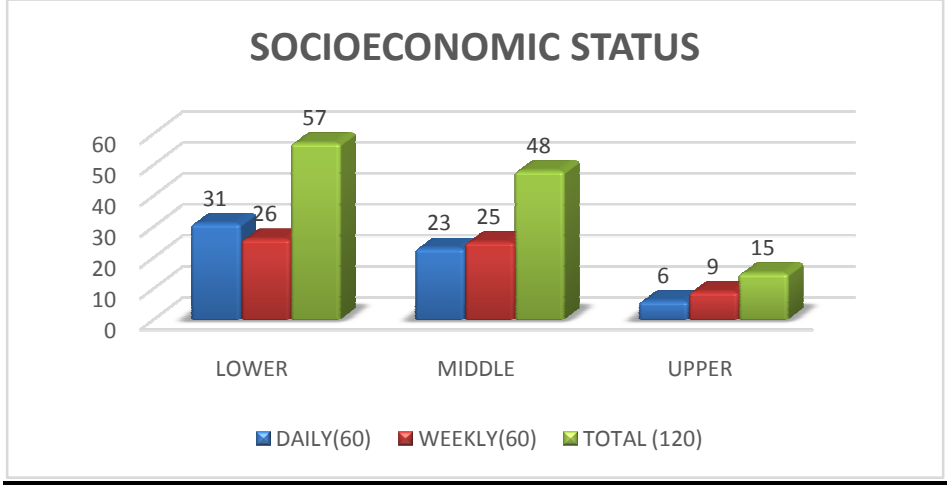


TABLE 9- DISTRIBUTION OF PATIENTS ACCORDING TO OBSTETRIC HISTORY

OBSTETRIC HISTORY	DAILY		WEEKLY		TOTAL	P VALUE
	n_1=60	%	n_2=60	%	n_1+n_2 = 120	
PRIMIGRAVIDA	29	48.33	34	56.67	63	0.464
MULTIGRAVIDA	31	51.67	26	43.33	57	
TOTAL	60	100	60	60	48	

The distribution of patients on the basis of obstetric history or parity in the present study was – primigravida were 29 (48.33%) and multigravida were 31 (51.67%) pregnant women in daily group. In weekly group 34 (56.67%) were primigravida and 26 (43.33%) were multigravida. There was no statistical difference between the two groups. (**Table 9; Figure 9**)

FIGURE 9- DISTRIBUTION OF PATIENTS ACCORDING TO OBSTETRIC HISTORY

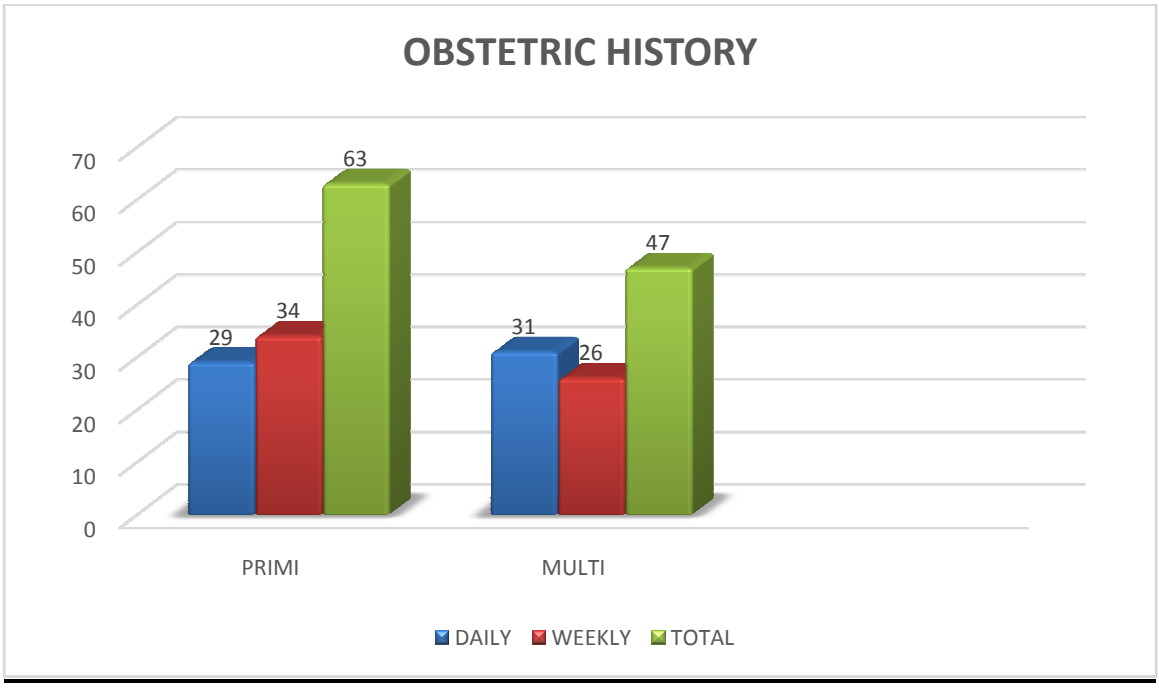


TABLE10-DISTRIBUTION OF PATIENTS ACCORDING TO SOCIODEMOGRAPHIC FACTORS

PARAMETERS	SUBGROUP	DAILY REGIMEN n_1=60	%	WEEKLY REGIMEN N_2=60	%	TOTAL n_1+n_2=120	%	p value
AGE (years)	≤20	5	8.33	6	10	11	9.17	0.157
	21-30	51	85	45	75	96	80	
	>30	4	6.67	9	15	13	10.83	
RELIGION	Hindu	53	88.34	52	86.67	105	87.5	0.157
	Muslim	5	8.33	5	8.33	10	8.33	
	Others	2	3.33	3	5	5	4.17	
LOCALITY	Rural	32	53.33	31	51.67	63	52.5	1
	Urban	28	46.67	29	48.33	57	47.5	
EDUCATION	Illiterate	28	46.67	25	41.67	53	44.17	0.157
	Primary education	20	33.33	20	33.33	40	33.33	
	Middle school	6	10	10	16.67	16	13.33	
	High school	5	8.33	3	5	8	6.67	
	Graduate	1	1.67	2	3.33	3	2.5	
OCCUPATION	Housewife	51	85	53	88.33	104	86.67	0.789
	Working	9	15	7	11.67	16	13.33	
SOCIOECONOMIC STATUS	Lower	31	51.67	26	43.33	57	47.5	0.464
	Middle	23	38.33	25	41.67	48	40	
	Upper	6	10	9	15	15	12.5	
OBSTETRIC HISTORY	Primi gravida	29	48.33	34	56.67	63	52.5	0.464
	Multi gravida	31	51.67	26	43.33	57	47.5	

TABLE 11- COMPARISION OF MEAN HEMOGLIBIN BETWEEN DAILY AND WEEKLY GROUPS

TIME	DAILY	WEEKLY	t VALUE	p VALUE
VISIT 1	10.83±0.64	11.04±0.91	1.462	0.146
VISIT 2	11.31±0.73	11.40±0.76	-0.572	0.569
VISIT3	11.79±0.83	11.58±0.84	-1.377	0.170

In the present study, hemoglobin values at the time of entry in study was taken as Visit 1 which was 10.83±0.64 in daily group and 11.04±0.91 in weekly group and p-value 0.146 which is not statistically significant. In Visit 2 after one month of iron supplementation, daily group mean hemoglobin was 11.31±0.73 where as weekly group was 11.40±0.76 and p-value 0.569 which is not statistically significant. In Visit 3 mean hemoglobin was 11.79±0.83, in weekly group 11.58±0.84 and p-value 0.170 which is not statistically significant. Overall raise in hemoglobin level is found to be comparable in both the groups and as such no statistical significance. (**Table11; Figure10**)

FIGURE 10- COMPARISION OF MEAN HEMOGLIBIN BETWEEN DAILY AND WEEKLY GROUPS

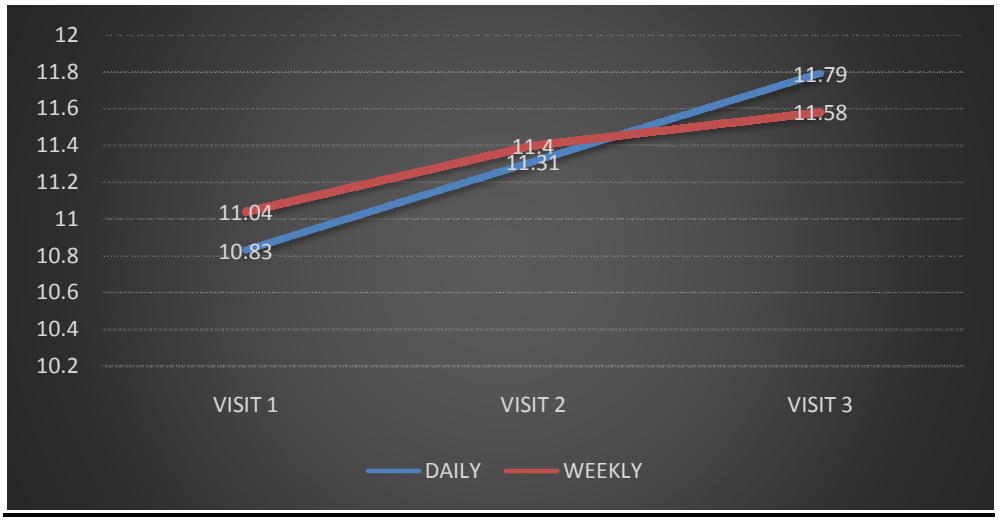


Table 12- COMPARISON OF RISE IN MEAN HEMOGLOBIN BETWEEN DAILY AND WEEKLY GROUPS

REGIMEN	VISIT 1	VISIT 2	VISIT 3	DIFFERENCE	t -value	p VALUE
DAILY REGIMEN	10.83±0.64	11.31±0.73	11.79±0.83	0.960	7.095	<0.0001
WEEKLY REGIMEN	11.04±0.91	11.40±0.76	11.58±0.84	0.540	3.378	<.001

The rise in haemoglobin in daily group was from 10.83±0.64 to 11.79±0.83 (3rd visit) with a **significant p value of <0.0001**. There was significant rise of haemoglobin in weekly group also from11.04±0.91 to 11.58±0.84 (p value<0.001). However, rise was more in daily group rather than weekly group.(**Table- 12, Figure-11**)

FIGURE 11 - COMPARISON OF RISE IN MEAN HEMOGLOBIN BETWEEN DAILY AND WEEKLY GROUPS

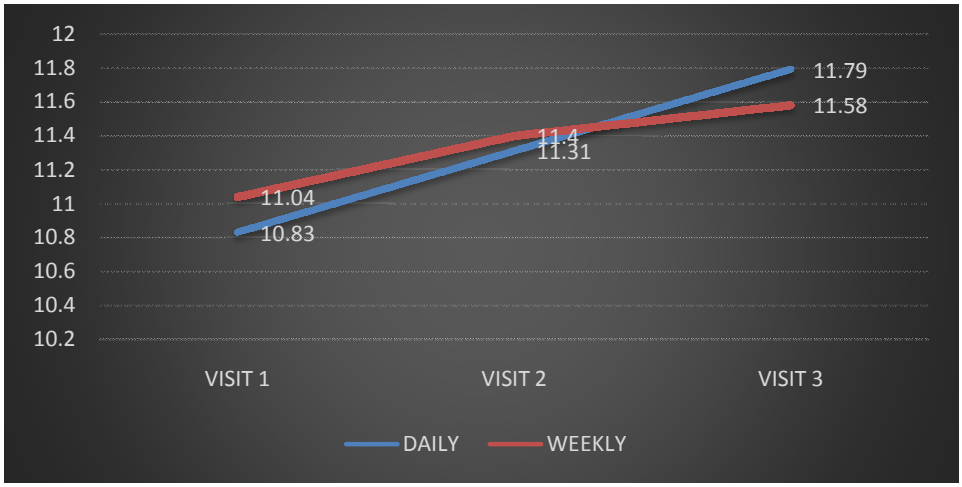


Table 13- COMPARISON OF RISE IN SERUM FERRITIN BETWEEN DAILY AND WEEKLY REGIMEN

REGIMEN	VISIT 1	VISIT 2	VISIT 3	DIFFERENCE	t VALUE	p VALUE
DAILY REGIMEN	50.04±29.67	82.40±30.11	117.41±20.25	67.370	14.527	<0.0001
WEEKLY REGIMEN	58.80±36.38	58.90±26.51	70.68±24.10	11.880	2.109	<0.0371

The rise in serum ferritin in daily group was from 50.04±29.67to 117.41±20.25 (3rd visit) with a significant p value of <0.0001. There was rise of ferritin in weekly group also from 58.80±36.38 to 70.68±24.10 (p value<0.0371). However, rise in weekly group was not significant.(**Table- 13, Figure-12**)

FIGURE 12-COMPARISON OF RISE IN SERUM FERRITIN BETWEEN DAILY AND WEEKLY REGIMEN

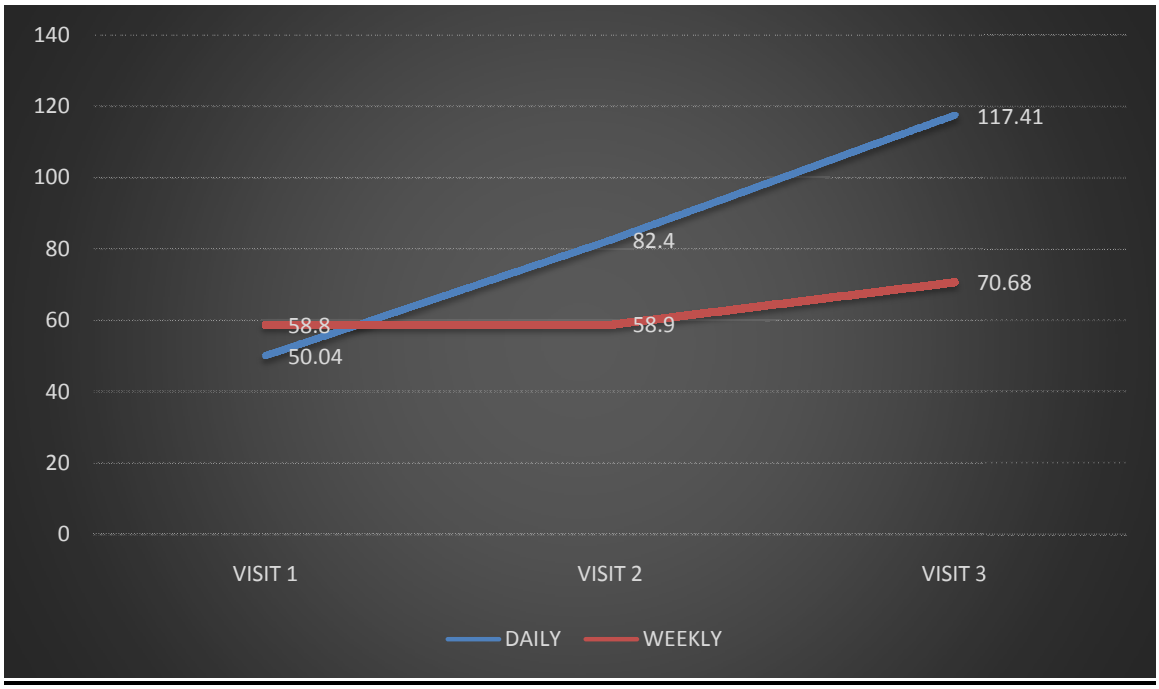


TABLE -14 SIDE EFFECTS OF DAILY ORAL IRON

SIDE EFFECTS	NUMBER (n=60)	PERCENTS (%)
NAUSEA	17	28.33
VOMITING	9	15
CONSTIPATION	3	5
GASTRITIS	1	1.6
DIARRHOEA	3	5
METALLIC TASTE	2	3.33
NO SIDE EFFECTS	25	41.67

In the present study, in the daily group 17 pregnant women were suffering from nausea , 9 from vomiting, 3 were suffering from constipation , 1 pregnant woman was having gastritis, 3 from diarrhoea and 2 were having bad taste whereas 25 were having no side effects at all. Majority of the complications were gastro-intestinal in nature. (**Table 14; Figure 13**)

FIGURE 13- SIDE EFFECTS OF DAILY ORAL IRON

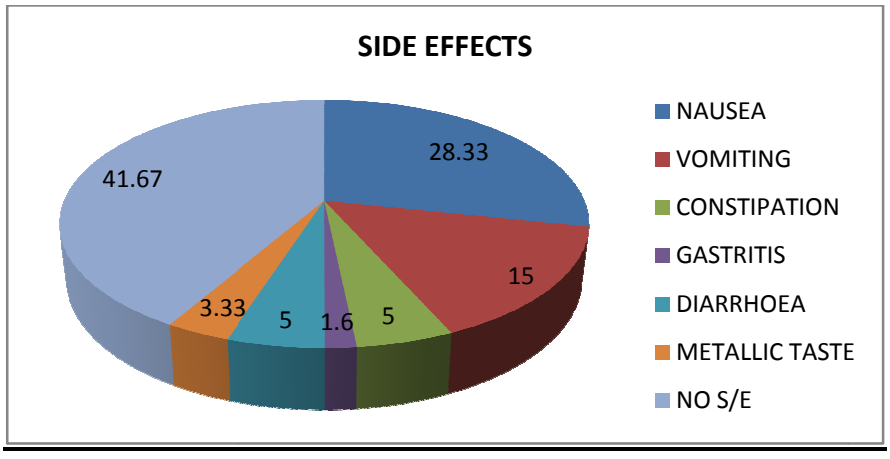


TABLE 15- SIDE EFFECTS OF WEEKLY ORAL IRON

SIDE EFFECTS	NUMBER (n=60)	PERCENTS (%)
NAUSEA	4	6.6
VOMITING	1	1.67
CONSTIPATION	2	3.33
GASTRITIS	0	0
DIARRHOEA	0	0
METALLIC TASTE	1	1.67
NO SIDE EFFECTS	52	86.67

In the present study, in the weekly group 4 pregnant women were suffering from nausea ,1 from vomiting 2 were suffering from constipation , 1 was having bad taste whereas 52 were having no side effects at all. Due to less side effects compliance was good. (**Table 15 ; Figure 14**)

FIGURE 14- SIDE EFFECTS OF WEEKLY ORAL IRON

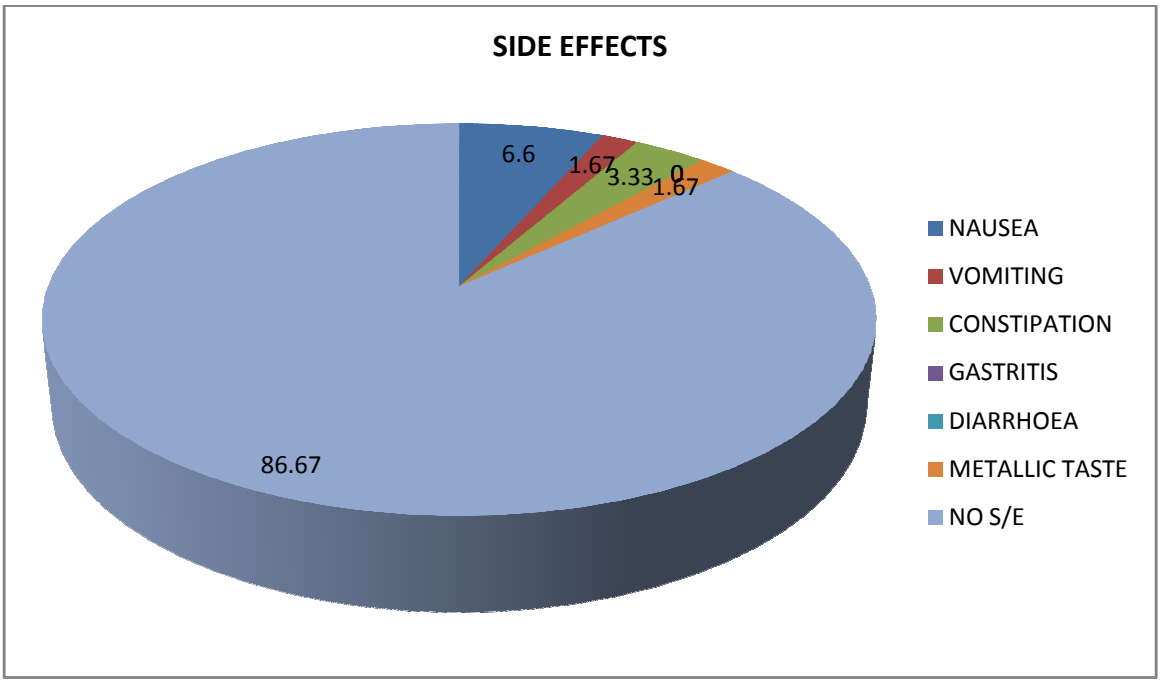


TABLE 16- COMPARISON OF ADVERSE EFFECT- NAUSEA

NAUSEA	DAILY		WEEKLY		P VALUE
	n_1=60	%	n_2=60	%	
PRESENT	17	28.33	4	6.67	
ABSENT	43	71.67	56	93.33	<0.003
TOTAL	60	100	60	100	

In the present study nausea was present in 17 (28.33%) pregnant women in daily group but it was very less in weekly groups 4 (6.67%) which is **highly statistically significant**.(P value **<0.003**) (**Table 16 ; Figure15**)

FIGURE 15- COMPARISION OF ADVERSE EFFECT- NAUSEA

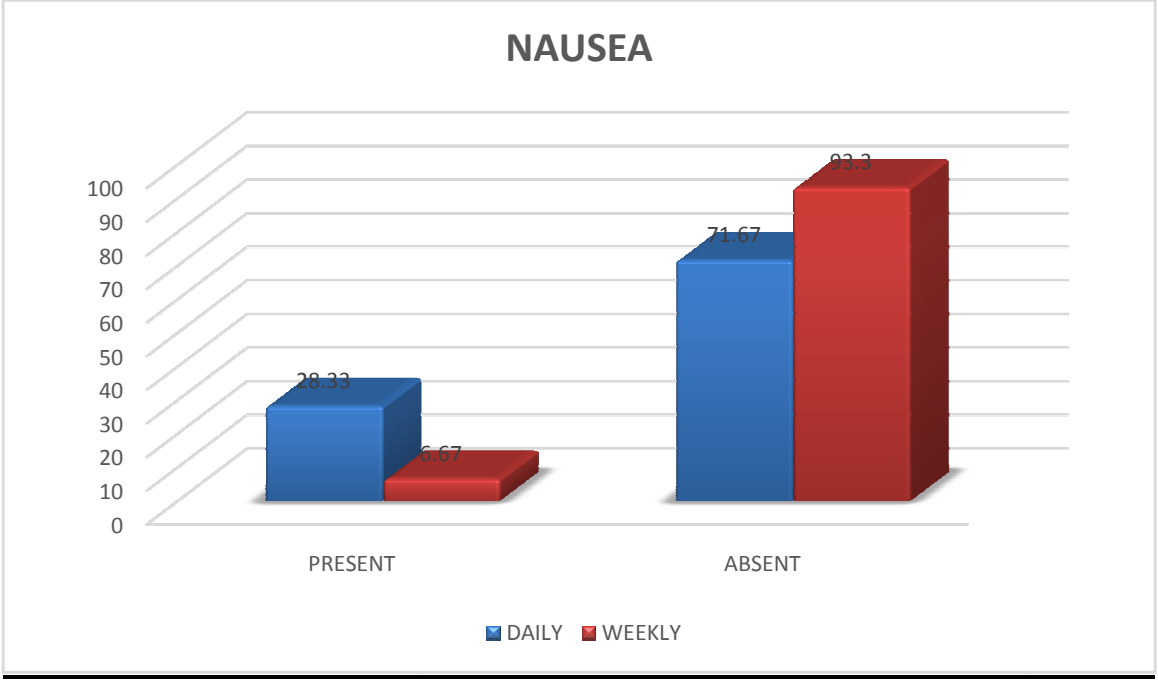


TABLE 17- COMPARISON OF ADVERSE EFFECT-VOMITING

VOMITIG	DAILY		WEEKLY		P VALUE
	n_1=60	%	n_2=60	%	
PRESENT	9	15	1	1.67	<0.0008
ABSENT	51	85	59	98.33	
TOTAL	60	100	60	100	

In the present study in daily group vomiting was present in 9(15 %) pregnant women but it was very less in weekly groups; 1 (1.67%) which is **statistically significant**. P value is **<0.0008**. (**Table 17 ; Figure 16**)

FIGURE 16- COMPARISON OF ADVERSE EFFECT-VOMITING

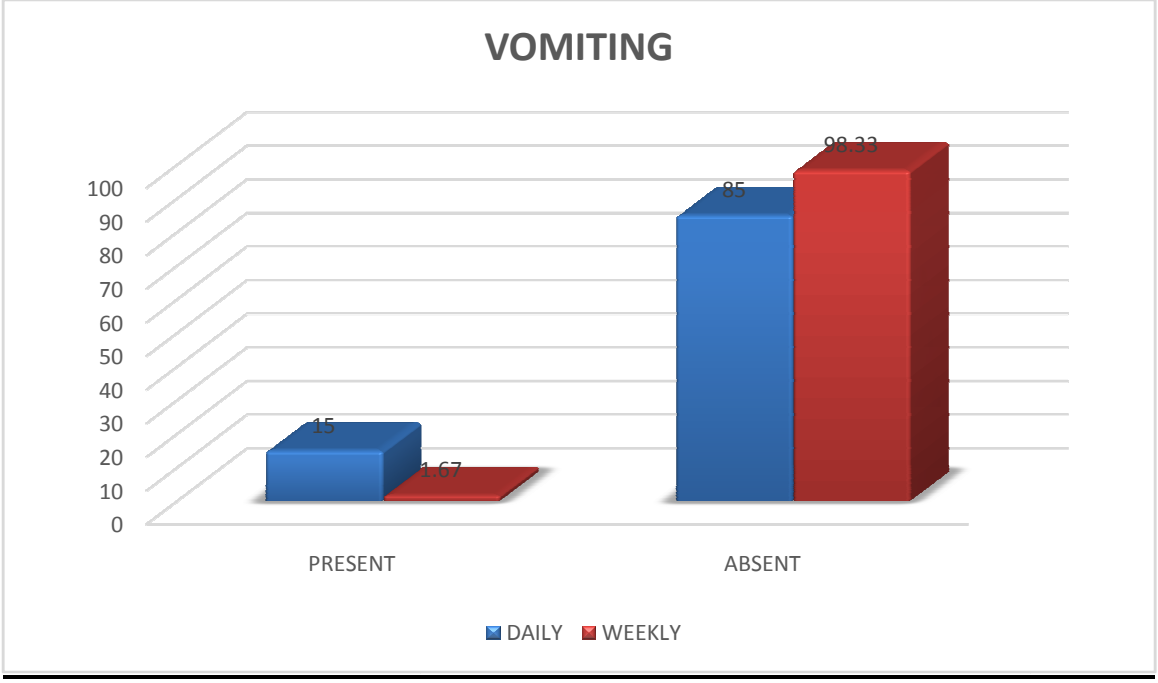


TABLE 18- COMPARISON OF ADVERSE EFFECT-CONSTIPATION

CONSTIPATION	DAILY		WEEKLY		P VALUE
	n_1=60	%	n_2=60	%	
PRESENT	3	5	2	3.33	1
ABSENT	57	95	58	96.67	
TOTAL	60	100	60	100	

In the present study in daily group constipation was present in 3 (5%) pregnant women and it was present in 2 (3.33%%) patients in weekly groups; which is not statistically significant. P value is 1. (Table 14; Figure 17)

FIGURE 17- COMPARISON OF ADVERSE EFFECT-CONSTIPATION

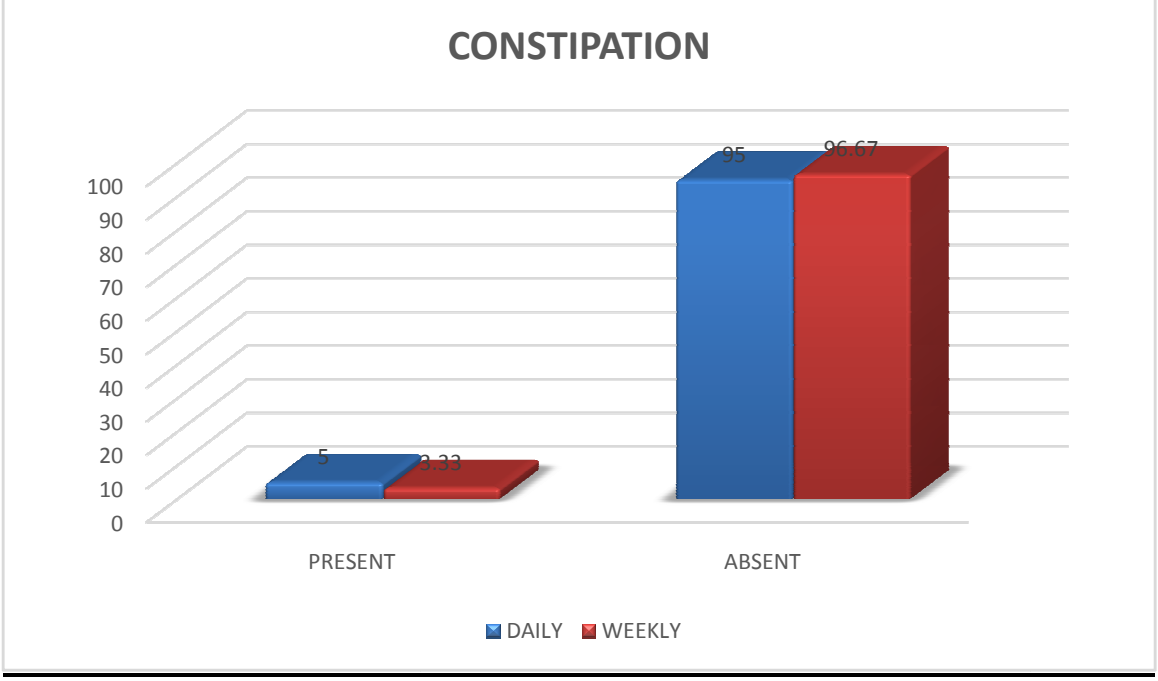


TABLE 19- COMPARISON OF ADVERSE EFFECT-GASTRITIS

GASTRITIS	DAILY		WEEKLY		P VALUE
	n_1=60	%	n_2=60	%	
PRESENT	1	1.67	0	0	
ABSENT	59	98.33	60	100	1
TOTAL	60	100	60	100	

In the present study in daily group gastritis was present in 1 (1.67%) pregnant women but it was absent in weekly group. (P value is 1) ; (**Table 19; Figure 18**)

FIGURE18- COMPARISON OF ADVERSE EFFECT-GASTRITIS

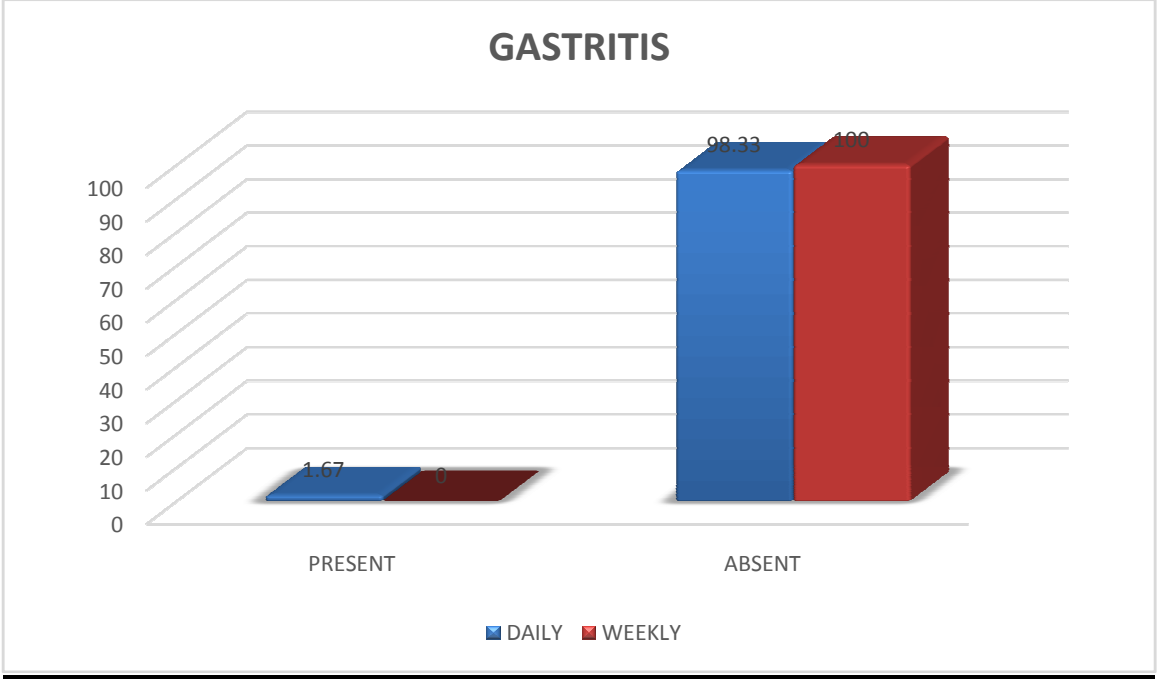
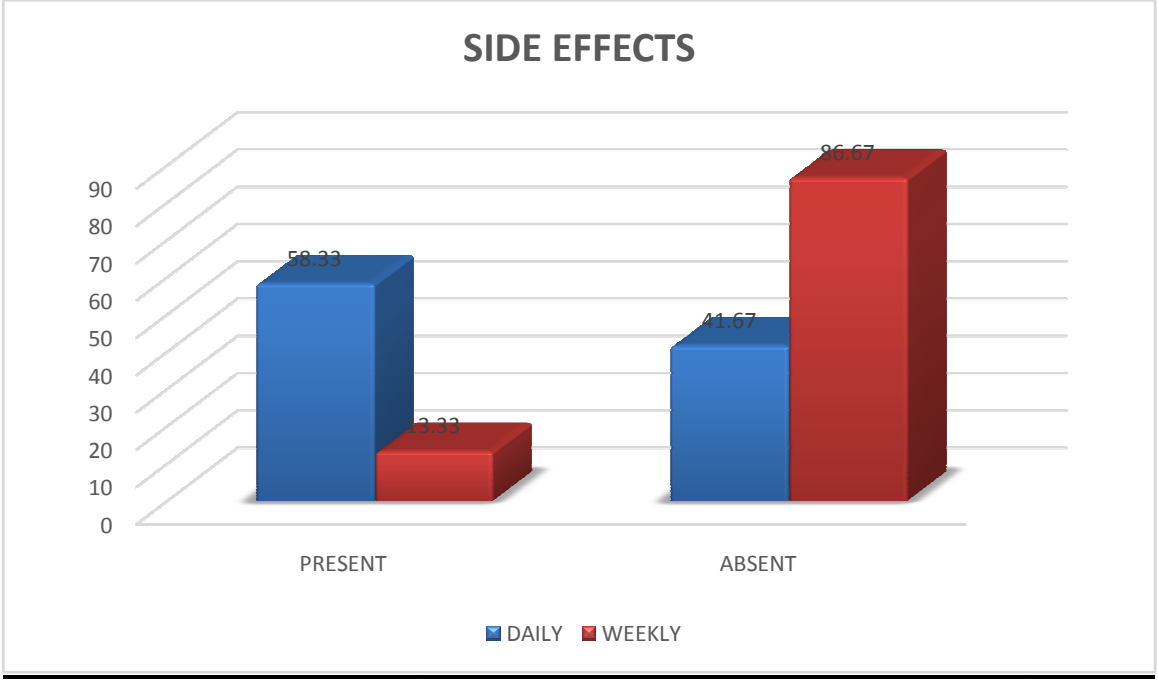


TABLE 20 - COMPARISON OF OVERALL SIDE EFFECTS IN DAILY AND WEEKLY REGIMEN

OVERALL SIDE EFFECTS	DAILY REGIMEN		WEEKLY REGIMEN		p value
	n_1 =60	PERCENT	n_2 = 60	PERCENT	
PRESENT	35	58.33	8	13.33	
ABSENT	25	41.67	52	86.67	
TOTAL	60	100	60	100	<0.0001

The overall side effects of daily regimen were much higher than weekly group; daily had 58.33% side effects where as weekly had cases merely of 13.33% which is statistically significant. (p value- <0.0001)**(Table-20; Figure- 19)**

FIGURE 19 - COMPARISON OF OVERALL SIDE EFFECTS IN DAILY AND WEEKLY REGIMEN



DISCUSSION

Iron deficiency due to inadequate nutritional status is the single most leading reason for iron deficiency anemia in the world. More than 2 billion people suffer worldwide[1]. In India 62-88% pregnant women suffer from iron deficiency[2]. Though considerable efforts are being done to decrease its occurrence in the last three decades still it is prevalent.

Primary focus is to increase the store, bioavailability and to increase immunity. Nutritional deficiency is highest in populations where peak rate of growth is seen due to increased demand namely infants, young children, adolescents and pregnant women. Pregnancy is a state where iron deficiency develops maximally due to increased demand and more so in the second half of pregnancy[1].

Despite wide spread preventive programs; iron deficiency is prevalent in pregnancy which adversely affects maternal and neonatal outcomes. Poor client compliance to National iron supplementation protocols because of its side effects, especially gastro intestinal complications like nausea, vomiting, constipation etc is seen. There is experimental evidence that iron absorption is reduced in rats in the days immediately after the initial administration of a large dose of iron but is resumed after ≈3 days. It was therefore argued that the administration of iron weekly or twice weekly would be both more rational and cost-effective with fewer side effects[9]. Hence studies have been done which indicate that intermittent iron supplementation rather than daily might improve absorption due to enhanced compliance due to lesser side effects[73].

Although iron is supplied routinely as daily regimen from 4th month onwards in pregnancy as standard antenatal care, iron deficiency is a commonly reported complication. We carried out our study to examine the efficacy and tolerability of weekly versus daily iron supplementation during pregnancy and presenting it as an alternative method for prevention of iron deficiency and decreasing side effects related to daily supplementations thereby enhancing maternal compliance, decreasing financial burden and improving fetal outcome overall.

There was no statistical significant difference between the daily and weekly groups with respect to socio demographic parameters like age, religion, locality, educational qualification, socio economic status, parity, and mean hemoglobin levels as p value in all the parameters were greater than 0.05 (by using fisher's exact and chi square test).

The mean age in our study in daily and weekly regimens was 26.03± 3.60 and 26.30±3.25 respectively. This was comparable to other studies. In the study by Rajoria L et al[1] and Siabani S et al[5]the mean age was 25.1±5.6 and 27.86 ± 5.54 respectively. Maternal age (years) 22.7±3.9 and 22.4±3.8 respectively in both the groups in study done by Magdy Abdelgawad et al[72]. In the study conducted by Iglesias VL et al[4] mean age was 30.40±5.07 and 30.21±5.28 respectively. There is slight disparity between the mean age of this study with our study as it was done in Spain where mean age of marriage and child birth is higher due to industrialization and many women belonging to working class. Ahmadreza Z et al[59] had age group between 18- 38years. In study conducted by Ameet Patki et al[49] mean age for daily and weekly groups were 22.63±4.07 and 24.56±3.29 respectively. This was comparable to our study. All the studies done in India or Asian countries were having similar mean age where as western world has higher mean age. But all fall into reproductive age group of 20 -40 years.

In our study there was no significant difference in any religious group. Likewise studied done in western world and Middle East also showed no significance related to different religious group76.

In our study in the daily group primigravida were of 48.33% and multigravida was 51.67% with a p value 0.464 which are statistically not significant. This was comparable to study conducted by Rajoria et al[1] where the mean parity was 1.8±0.9. Magdy Abdelgawad et al[72] studied parity with p value of 0.487 which was similar to our study. In a study done by Siabani S et al[5], primigravida were 51% and multigravida were 49%. But our results vary from the result obtained in the study done by Loy SL et al68where they primigravida were 56.67% and multi gravida were 43.33%.

In our study the literacy rate in daily group is 46.67% and in weekly group is 41.67%. and the literacy rate in daily group is 53.33% and in weekly group is 58.33% which is completely different from studies done in European and middle East countries[76].

In our study 85% of the study population was housewives and 15% belonged to working class in daily group. And in weekly group the housewives were 88.33% and working class were 11.67% which was comparable to the study done by S, Siabani H, Moeini Arya M,et al[5] where 90.3% of the study population were housewives and 9.7% were working class.

In our study in the daily group 16.4% belonged to lower SES, 66.7% to middle SES and 16.9% to upper SES which was different from the study conducted by Iglesias et al[4] where these numbers were 51.67%, 38.33% and 10% respectively. Similarly in weekly group 15.6% belonged to lower SES, 67.6% to middle SES and 16.8% to upper SES and in the study conducted by Iglesias et al[4] these numbers were 43.33%, 41.67% and 15% respectively.

In our study the hemoglobin rise was more significant in daily group, but it also increased to a significant level ($p<0.0001$) in weekly group as well and was maintained to a safe level. In studies by Bagchi et al[2] and Mumtaz et al[69]too, the hemoglobin rose to a significant level in weekly group ($p=0.001$ and $p=0.0037$ respectively).

Serum ferritin value is a very sensitive indicator of iron storage status which did not increase to a significant level ($p=0.0371$) in weekly group in our study but in daily group the increase was significant ($p<0.0001$). Similar results were found in the study done by Bagchi et al[2] and Mumtaz et al[69]where the serum ferritin levels were increased to a significant level in daily group ($p<0.001$ each) whereas in weekly group it did not change ($p=0.0661$ and $p=0.16$ respectively). In the study by A. Mukhopadhyay et al[50] there was no significant increase in S. ferritin values in both daily ($p=0.477$) and weekly group ($p=0.680$). In study by Ridwan et al[46], there was a small decrease in the weekly group along with a small increase in the daily group, which caused a small but significant difference between groups in treatment effect ($p=0.049$).

Hence it was seen that though hemoglobin increased to a significant level in daily and weekly supplemented group in most of the studies; but S. ferritin values showed values increased to a significant level in the daily group in most of the studies but in weekly supplemented group it either did not change or decreased.

In our study there were significant differences between the daily iron supplement group and the weekly iron supplement group in terms of complications. Nausea was the most common complication in daily regimen group (28.33%) and also in the weekly regimen group (6.67%). Vomiting was the second most common complication in the daily regimen group (15%) whereas constipation was the second most common complication in the weekly regimen group (3.33%). Vomiting was seen only in 1.67% of women of weekly regimen group. Constipation was seen in 5% women in daily regimen group. Both vomiting and constipation was more prevalent in daily regimen group then weekly regimen group. Gastritis was seen in 1.67% women in daily regimen group whereas it was absent in weekly regimen group. Diarrhea was seen in 5% of women in daily regimen group but it was not seen in weekly regimen group. 3.33% of women in daily regimen group experienced metallic taste which was seen only in 1.67% of women in weekly regimen group. In weekly regimen group most women did not show any side effects (86.67%) where as in the daily regimen group only 41.67% women did not show any side effects, which was highly statistically significant ($p<0.0001$). Similarly in studies done by Siabani S, et al[5], Ogundipe O et al[75] and Ugwu EO et al[76] had shown poor compliance to daily iron supplementation due to gastrointestinal side effects.

SUMMARY

Anemia is a frequent condition during pregnancy, particularly among women from low- and middle-income countries who have insufficient iron intake to meet increased iron needs. Traditionally, pregnancy anemia has been prevented with the provision of daily iron supplements. However, it has newly been suggested that if women take supplements less often, such as once or twice weekly rather than daily, this might decrease side effects and enhance acceptance and adherence to supplementation. In this review we assessed the benefits and harms of intermittent (once weekly) oral supplementation with iron.

This prospective Randomized study was conducted in Obstetrics and Gynecology department of Santosh Hospital, Ghaziabad. This study was done to compare changes in hemoglobin percentage with weekly versus daily iron supplementation of iron, which is well tolerated and effective in pregnant women. Approval was obtained from Ethics Committee and consent was taken from each patients. Apparently healthy anemic pregnant women of 13 to 28 weeks of gestation with hemoglobin level ≥ 10.0 g/dl were included in the study. Women with multiple pregnancies, hemoglobin level < 9.0 g/dl, with chronic systemic disorder or with any high risk factor were excluded. Baseline hemoglobin and serum ferritin level monitoring was done. Patients were given dietary advice. They were instructed to take iron after food and to avoid tea and coffee before iron intake. They were explained about the possible side effects and also were informed about subsequent visit. Detailed follow up was done in respect to patients' compliance and side effects of taking both regimens of oral iron. Total numbers of pregnant women were 120 between gestational age 13 and 28 weeks and were divided into two groups, group-A receiving 60 mg of elemental daily (420 mg/week) and group –B receiving 120 mg of elemental weekly iron respectively. Rise in hemoglobin percentage and serum ferritin were checked, after 4 weeks and finally at the time of delivery, to note the improvement. Subsequently side effects were noted and corrective measures were taken. They were advised to continue iron tablets 3 months postpartum. Data obtained was analyzed by ANOVA and Chi- Square Test. P value< 0.005 is considered statistically significant.

Looking at its findings (intermittent regimen including iron versus a daily regimen), there was no clear evidence of differences between both groups in terms of socio demographic parameters. Majority of patients were between 20-30 years of age with mean age of the patients in daily group 26.03± 3.60 and mean age in weekly group 26.30±3.25.

The rise in hemoglobin in daily group was from 10.83±0.64 to 11.79±0.83 (3rd visit) with a significant p value of <0.0001. There was significant rise of hemoglobin in weekly group also from11.04±0.91 to 11.58±0.84 (p value<0.001). However, rise was more in daily group rather than weekly group.

The rise in serum ferritin in daily group was from 50.04±29.67to 117.41±20.25 (3rd visit) with a significant p value of <0.0001. There was rise of ferritin in weekly group also from 58.80±36.38 to 70.68±24.10 (p value<0.0371). However, rise in weekly group was not significant.

Patients who received daily iron supplements had more side effects as compared to those who had intermittent regimen. 58.33% percentage of daily group experienced some or the other side effects mainly in the form of gastro intestinal side effects like nausea, vomiting, diarrhea, constipation and metallic taste etc. This was contrary to only 13.33% in weekly group. The difference was significant (p value <0.0001).

Thus it was concluded that although there was higher increase in hemoglobin and serum ferritin levels in patients with daily supplementation of iron, but that is under ideal circumstances when patient is complaint to therapy and takes iron on daily basis. However this can be achieved if iron is given under supervision daily by health care workers. But this is not practically possible in resource poor country like India. On the other hand the increase in hemoglobin was also seen in weekly group with marginal rise in serum ferritin level. But the side effects were much lower in weekly group as compared to daily group. This can be taken as a benefit in improving the compliance of the patients and hence maintaining the hemoglobin levels throughout pregnancy.

CONCLUSION

The conclusion of this prospective randomized control trial is that daily and weekly administration iron supplement in non-anemic pregnant women has similar hematological response. Regarding the side effects of iron supplementation, weekly supplementation seems preferable to daily intake .There is also improved compliance to the therapy and reduced cost of supplementation.

Also intermittent supplementation showed to reduce the number of women with increased hemoglobin concentrations during mid and late trimester compared with daily regimens thereby reducing the unacceptable high hemoglobin concentrations which are harmful as they may be associated with an increased risk of having a premature birth and low birth weight baby.

Thus weekly supplementation of non-anemic pregnant women with 120mg of elemental iron is an helpful alternative to daily regimen for prophylaxis.

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CASE PROFORMA

Name- Age- Registration no-

Occupation- Marital Status-

Husband's Name- Occupation of husbands-

Address-

Socio-Economic Status-

Mobile no- Religion-

Parity- Gestation of Pregnancy-Preterm/Term/Post dated

EDD-

1st sample collection date-

2nd sample collection date-

3rd sample collection date-

CLINICAL DETAILS

Complaints-

Previous menstrual history-

Obstetrics history-

Past history-

Allergy history-

Medical/Surgical history-

1st Visit:

Physical Examination:

Temperature-	Pulse Rate-	BP-
Pallor-	Icterus-	Cyanosis-
Clubbing-	Lymphadenopathy-	
Edema-	Height-	Weight-

Respiratory System-

Cardiovascular System-

CNS-

Per Abdomen-

Per Speculum-

Per Vaginum-

INVESTIGATION:

CBC-

Serum Ferritin Level-

TREATMENT GIVEN:

Intravenous Iron/Oral Iron

Dosage

2nd Visit:

Complaints-

Physical Examination:

Temperature- Pulse rate- BP- Pallor-

P/A- P/S- P/V-

INVESTIGATION:

CBC-

Serum Ferritin-

TREATMENT GIVEN:

Intravenous Iron/Oral Iron

Dosage

3nd Visit:

Complaints-

Physical Examination:

Temperature- Pulse rate- BP- Pallor-

P/A- P/S- P/V-

INVESTIGATION:

CBC-

Serum Ferritin-

TREATMENT GIVEN:

Intravenous Iron/Oral Iron

Dosage

INFORMED CONSENT

Name of the patient: Age:

Address: Phone Number:

S.NO: Date:

I have been explained the details of the study entitled **"A comparative study of conventional daily versus low dose weekly oral iron supplementation in preventing anemia during pregnancy"** and my questions regarding the study have been answered to my satisfaction in a language understood by me.

1. I understand that I have the right to withdraw from the study at anytime and to decline to answer any particular question.
2. I understand that my participation in this study is confidential and that no material that could identify me will be used in the analysis and in any reports based on this study.

I hereby provide my consent in the study entitled **"A comparative study of conventional daily versus low dose weekly oral iron supplementation in preventing anemia during pregnancy**".

Signature/ thumb impression of the patient

Signature/ thumb impression of witness

सूचितसहमति

गाइड का नाम: -

रोगी का नाम: आयु:

पता: -

फ़ोन नंबर:-

एस एन ओ:

मुझे □ ध्ययन के विवरण समझाया गया है & "**A comparative study of conventional daily versus low dose weekly oral iron supplementation in preventing anemia during pregnancy**"मेरा □ ध्ययन के बारे में प्रश्नों को एक मेरे द्वारा समझा भाषा में मेरी संतुष्टि का उत्तर दिया गया

1. मैं समझता हूं कि मुझे किसी भी समय□ ध्ययन से वापस लेने का □ धिकार है और किसी विशेष प्रश्न का उत्तर देने में गिरावटआई है।

2. मैं समझता हूं कि इस □ ध्ययन में मेरी भागीदारी गोपनीय है और सामग्री जो मुझे पहचान सकती है और रिपोर्ट इस □ ध्ययन के आधार पर किसी भी में विश्लेषण उपयोग नहीं की जाएगी।
मैं इस प्रकार □ ध्ययन में □ पनी सहमति प्रदान करता हूं "एटियोलॉजिकल और नैदानिक पैटर्न का विश्लेषण बांझपन के लिए इलाज की मांग करने वाले जोड़ों में "

रोगी के हस्ताक्षर / □ंगूठे की छाप गवाह के हस्ताक्षर / □ंगूठे की छाप

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F. No. SU/2021/1830[58] Dated: 17.07.2021

Subject: Grant of Ethical Clearance for Thesis Protocol Topic **"A COMPARATIVE STUDY OF CONVENTIONAL DAILY V/S LOW DOSE WEEKLY IRON SUPPLEMENTATION IN PREVENTING ANEMIA DURING PREGNANCY",** submitted by **Dr. Shams Jahan ,** MD/MS student of Batch 2020-2021, Department of **Obstetrics & Gynaecology**.

*****

With reference to his/her request for grant of Ethical Clearance for the Thesis Protocol entitled **"A COMPARATIVE STUDY OF CONVENTIONAL DAILY V/S LOW DOSE WEEKLY IRON SUPPLEMENTATION IN PREVENTING ANEMIA DURING PREGNANCY"**, **Dr. Shams Jahan** is informed that the Thesis Protocol submitted by him/her was considered by the **Screening Committee** of the Santosh Medical College & Hospital in its meetings held on 19.03.2021, 22.03.2021, 24.03.2021, 25.03.2021, 26.03.2021, 27.03.2021 and 06.04.2021. The recommendations of the **Screening Committee** were considered in detail by the Institutional **Ethics Committee** in its meeting held on **12.07.2021** and the same was **approved** by the **Ethics Committee**.

He /She is informed accordingly for further necessary action.

[Dr. V. P. Gupta]
REGISTRAR

SANTOSH (DEEMED TO BE UNIVERSITY) REGISTRAR GHAZIABAD, NCR DELHI

Dr. Shams Jahan
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1. The Vice Chancellor
2. The Dean, SMC&H
3. The Dean – Research
4. The Dean – Academics
5. The Director - IQAC
6. Dr Neelima Agarwal (Guide)
7. HOD of **Obstetrics & Gynaecology**

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KEY TO MASTER CHART

Respondent - R

Locality Rural : 1 Urban: 2

Religion- Hindu: 1 Muslim: 2 Others: 3

Maternal Education- Illiterate:1 Primary Education: 2 Middle school : 3

High School: 4 Graduate: 5

Occupation- Housewife: 1 Working: 2

Socioeconomic Status: Lower : 1 Middle: 2 Upper: 3

Obstetric History: Primi gravida: 1 Multi gravida: 2

Visits: First visit: V_1

Second visit : V_2(after 4 weeks of supplementation)

Third visit: V_3(at the time of delivery)

Complaints : Yes: 1 No: 2

Serial No	Respondant	Age	Religion	Locality	Maternal Education	Occuppation
1	R1	20	1	1	1	1
2	R2	27	1	1	1	1
3	R3	23	1	1	1	1
4	R4	26	1	1	1	1
5	R5	28	1	2	2	1
6	R6	20	2	1	5	1
7	R7	25	1	1	1	1
8	R8	20	1	2	1	1
9	R9	26	1	2	4	1
10	R10	27	1	1	2	1
11	R11	27	1	2	1	2
12	R12	28	1	1	1	1
13	R13	28	3	2	2	1
14	R14	24	1	2	3	1
15	R15	27	1	2	1	2
16	R16	21	1	2	1	1
17	R17	28	1	1	1	1
18	R18	25	1	2	2	2
19	R19	22	2	1	2	1
20	R20	27	1	1	1	1
21	R21	25	1	1	2	1
22	R22	36	1	1	1	2
23	R23	21	1	2	1	1
24	R24	23	1	1	3	1
25	R25	28	1	1	2	1
26	R26	28	2	2	2	1
27	R27	30	1	1	1	2
28	R28	25	1	2	1	2
29	R29	27	1	1	3	1
30	R30	25	1	2	2	1
31	R31	31	1	2	3	1
32	R32	24	1	1	1	2
33	R33	26	3	1	2	1
34	R34	28	1	2	1	1
35	R35	25	1	2	2	1
36	R36	26	1	2	1	1
37	R37	24	2	1	3	1
38	R38	26	1	1	2	1
39	R39	26	1	2	1	1
40	R40	24	1	2	1	1
41	R41	28	1	1	3	1
42	R42	20	2	1	2	1

43	R43	25	1	1	1	1
44	R44	20	1	1	1	1
45	R45	26	1	1	2	1
46	R46	27	1	2	1	1
47	R47	25	1	1	2	1
48	R48	26	1	1	1	2
49	R49	21	1	2	4	1
50	R50	23	1	1	1	1
51	R51	24	1	1	1	1
52	R52	19	1	2	2	1
53	R53	25	1	1	1	1
54	R54	23	1	2	4	2
55	R55	23	1	2	2	1
56	R56	26	1	1	4	1
57	R57	26	1	1	2	1
58	R58	26	1	1	4	1
59	R59	32	1	1	2	1
60	R60	20	1	2	2	1

MASTER CHART

GROUP A (CONTROL /HIGH DOSE/DAILY SUPPLEMENTATION)

Socioeconomic Status	Obstetric History	Gestational Age	Hb	
			V1	V2
1	1	14	11.4	11.8
1	1	12	11.8	12.2
1	2	16	11.6	11.8
1	2	14	12.1	12.4
1	1	14.4	11.4	11.6
2	1	16.7	12.2	12.8
1	1	18	12.2	12.8
2	1	18	12.1	12.6
1	1	20	10.6	10.4
2	1	19.2	11.3	12.1
1	2	13.2	10.8	11.2
2	1	14	11.2	10.9
2	2	15	10.6	10.8
3	2	12	10.2	10.8
2	2	12.4	10	10.2
3	1	16.3	10.7	10.8
2	1	23.2	10.2	11.1
3	1	24	11.2	11.4
1	2	24.4	10.4	10.9
1	2	15	10.3	10.6
1	2	17.3	10.5	10.8
1	1	12.3	11.2	11.4
1	1	12	10.8	11.2
1	1	13	10.6	10.4
2	2	14	10.2	10.6
2	2	18	11.2	11.6
2	1	20	11.2	11.4
3	2	16	10.3	10.6
1	2	17	10.2	10.8
3	2	13.4	11.2	11.6
2	1	12.6	10.8	11.2
2	1	14.3	11.2	11.6
1	1	16.2	10.6	10.8
2	1	16	11.2	11.4
2	1	18.2	12.1	12.6
2	1	15	12.6	12.8
3	1	14.2	11.4	11.6
1	2	20.4	10.4	10.6
2	1	21.2	11.2	11.8
2	1	22	11.6	11.8
2	1	14.4	11.4	11.6
1	1	16.7	12.2	12.8

3	1	18	12.2	12.8
1	1	18	12.1	12.6
3	1	20	10.6	10.4
2	1	19.2	11.3	12.1
2	2	17.3	10.5	10.8
2	1	12.3	11.2	11.4
2	1	12	10.8	11.2
1	1	13	10.6	10.4
2	1	18.4	10.4	10.6
1	2	16.2	11.2	11.8
1	1	18.3	10.5	10.8
3	2	18.4	10.2	10.4
1	2	16	11.2	11.6
2	1	14	10.3	10.6
1	2	16.4	11.4	11.8
1	1	18.3	10.4	10.8
2	1	16.2	10.6	11.2
1	2	21	10.4	11.1

	Serum Ferritin			Complaints			
V3	V1	V2	V3	Nausea	Vomiting	Constipation	Gastritis
12.6	60	90	110	1	1	1	2
12.6	78	105	106	1	1	2	2
12.2	76	82	100	1	1	2	2
13.4	79	87	105	1	1	2	2
12.4	67	83	98	1	1	2	2
13.1	52	79	97	2	2	2	2
13	55	69	99	1	2	2	2
12.8	49	60	108	1	2	2	2
10.6	45	62	87	1	1	2	2
11.8	45	65	110	1	1	1	2
12.4	54	59	122	1	2	1	1
13.2	52	53	121	1	1	2	2
11.6	47	63	109	2	2	2	2
11.6	42	76	104	1	1	1	2
10.8	43	44	97	1	1	2	1
10.9	44	67	98	1	1	2	1
11.3	47	62	99	1	1	2	1
12.1	48	65	108	1	1	2	2
11.2	60	87	98	1	1	2	2
11.2	57	79	98	1	1	1	2
11.3	51	85	100	1	1	2	2
11.8	55	88	112	1	1	2	2
11.6	50	82	113	2	2	2	2
10.4	49	80	96	2	2	2	2
10.8	44	70	112	2	2	2	2
11.8	53	73	110	2	2	2	2
12.8	59	75	101	2	2	2	2
11.2	52	72	98	2	2	2	2
11.4	58	67	104	2	2	2	2
11.8	52	89	114	2	2	2	2
11.4	56	88	108	2	2	2	2
12.3	60	86	119	2	2	2	2
11.2	61	83	108	2	2	1	2
11.8	65	87	112	2	2	1	2
13.4	62	90	124	2	2	2	2
13.6	64	90	122	2	2	2	2
12.8	60	90	125	2	2	2	2
11.2	55	64	118	2	2	2	2
12.4	54	87	121	2	2	2	2
12	59	84	115	2	2	2	2
12.4	63	67	119	1	1	2	2
13.1	64	80	128	2	2	2	2

13	64	81	128	1	2	2	2
12.8	60	75	125	1	2	2	2
10.6	59	79	102	1	1	1	2
11.8	59	69	99	1	1	2	2
11.3	52	66	102	1	1	2	2
11.8	55	67	109	1	1	2	2
11.6	52	55	107	2	2	2	2
10.4	48	89	93	2	2	2	2
11.4	49	87	108	2	2	2	2
12.6	57	68	114	2	2	2	2
11.6	47	55	104	2	2	2	2
10.5	46	54	101	1	1	1	1
11.8	52	64	110	1	1	1	1
11.2	48	63	111	2	2	2	2
12.4	59	65	121	2	2	2	2
11.4	49	76	122	2	2	2	2
12.4	53	90	111	2	2	2	2
12.6	9	78	107	2	2	2	2

Serial no	Respondant	Age	Religion	Locality	Maternal Education	Occupation	Socioeconc
1	R1	25	1	1	1	1	
2	R2	26	1	1	2	2	
3	R3	24	1	1	1	1	
4	R4	24	1	1	2	1	
5	R5	24	1	1	1	1	
6	R6	20	3	2	1	1	
7	R7	22	1	2	1	1	
8	R8	34	1	2	2	1	
9	R9	22	1	1	3	1	
10	R10	27	1	1	1	1	
11	R11	26	2	1	1	1	
12	R12	20	2	2	1	1	
13	R13	23	1	2	2	1	
14	R14	32	2	1	3	2	
15	R15	22	1	1	1	1	
16	R16	23	1	1	1	1	
17	R17	29	3	1	2	2	
18	R18	26	1	2	1	1	
19	R19	33	1	2	3	1	
20	R20	20	1	2	2	1	
21	R21	25	1	2	1	1	
22	R22	23	1	1	3	1	
23	R23	23	1	1	2	1	
24	R24	24	1	1	1	1	
25	R25	30	1	1	1	1	
26	R26	20	3	2	1	1	
27	R27	25	1	1	1	1	
28	R28	27	1	2	1	1	
29	R29	23	1	1	2	1	
30	R30	26	1	2	3	1	
31	R31	31	1	1	1	1	
32	R32	20	1	1	1	1	
33	R33	27	1	1	1	1	
34	R34	24	1	2	1	2	
35	R35	30	1	1	2	1	
36	R36	25	1	1	1	2	
37	R37	21	1	2	1	1	
38	R38	23	2	2	1	1	
39	R39	25	1	1	2	2	
40	R40	23	1	1	1	2	
41	R41	26	1	1	2	1	
42	R42	32	1	2	2	1	
42	R43	28	1	1	4	1	

42	R44	24	1	1	3	1	
42	R45	23	1	1	2	1	
42	R46	30	1	2	2	1	
42	R47	30	1	1	4	1	
42	R48	23	1	2	3	1	
42	R49	28	1	2	2	1	
42	R50	24	2	1	3	1	
42	R51	20	1	2	3	1	
42	R52	25	1	2	2	1	
42	R53	27	1	2	3	1	
42	R54	23	1	2	4	1	
42	R55	26	1	2	2	1	
42	R56	26	1	2	5	1	
42	R57	32	1	2	2	1	
42	R58	28	1	2	5	1	
42	R59	24	1	2	2	1	
42	R60	23	1	2	2	1	

MASTER CHART

GROUP B (TEST/LOW DOSE/WEEKLY SUPPLEMENTATION)

omic Status	Obstetric history	Gestational age	Hb			Serum Ferritin	
			V1	V2	V3	V1	V2
1	1	18	12.4	12	11.6	60	78
1	2	20	10.6	10.8	11	45	82
1	2	16.2	11.2	11.4	11.8	52	88
1	2	11.4	11	11.2	11.4	50	79
1	2	14.3	10.6	10.8	11.2	45	80
1	2	12.6	11.2	11.4	11.6	55	85
2	2	14.6	10.4	10.8	11	46	81
2	2	12.6	11.2	11.4	12	54	88
2	1	14.2	11.4	11.6	12	52	88
2	1	16	10.4	10.8	11	46	79
2	1	13.2	11.4	11.6	11	57	76
3	1	14.3	10.8	11	11	47	76
1	2	14.5	10.6	11	11.2	48	79
2	2	16	12.1	11.8	11.6	58	84
2	1	14.6	10.2	10.2	10.4	43	74
2	1	15.3	13.2	12.8	13	60	95
1	2	12.1	12.4	11.8	10.8	57	73
1	1	14.2	11.8	10.9	11.6	53	78
1	1	12	13.6	13	13.2	58	92
1	1	13	11.2	10.8	10.6	54	76
1	2	14.4	11.4	11.8	11.9	49	67
2	2	12.6	10.6	11.2	12	44	64
2	1	18	10.8	11	11.2	45	62
1	1	20	10.4	11	11.4	42	61
2	1	22	11.2	11.4	11.6	47	68
1	2	14	10.8	10.6	11	44	72
1	1	16.3	10.6	10.8	10.9	48	76
1	1	16.4	10.2	10.4	10.9	43	73
2	2	18.6	10.1	10.3	10.4	42	83
1	2	14.2	10.3	10.4	10.8	46	81
1	1	13	11.4	12	12.6	52	85
1	1	12	12.3	12.5	13	55	82
1	1	20	10.6	12.6	12.8	51	84
1	1	19	11.6	11.8	12.2	58	76
3	1	24	11.4	11.8	12.4	55	87
2	1	18	12.1	12.4	13	58	88
2	1	17	12.6	13	13.2	60	90
2	1	14	12.4	12.8	13	55	88
1	2	12	10.8	11.4	11.8	48	79
1	1	12.3	12.8	12.8	13	49	90
1	2	11.2	10.2	10.9	11.3	51	72
1	1	18	10.4	10.8	11.2	40	74
1	1	14.2	10.3	11.4	11.6	46	85

1	1	11.4	11.2	11.6	12.1	52	82
2	2	12.6	10.4	11.6	12.8	45	79
2	2	18	10.6	10.4	10.8	44	75
2	1	13.4	10.2	11.2	11.6	46	78
1	2	12.4	10	10.8	11	40	75
1	1	14.4	10.8	11	11.6	48	79
1	2	14.2	11.2	12	12.4	48	82
1	2	14	10.8	10.9	11	49	81
2	1	16.3	10.1	10.2	10.6	49	43
2	1	16.4	10.2	10.4	10.9	43	89
2	2	18.6	10.1	10.3	10.4	44	85
2	2	14.2	10.3	10.4	10.8	50	74
2	2	11.2	10.2	10.9	11.3	49	75
3	1	18	10.4	10.8	11.2	48	75
3	1	14.2	10.3	11.4	11.6	49	83
3	1	11.4	11.2	11.6	12.1	56	82
3	2	12.6	10.4	11.6	12.8	47	85

	Complaints			
V3	Nausea	vomiting	Constipation	Gastritis
72	2	2	2	2
72	2	2	1	2
78	2	2	2	2
81	2	2	2	2
82	2	2	2	2
86	2	2	2	2
75	1	2	1	2
72	2	2	2	2
78	2	2	2	2
79	2	2	2	2
72	1	1	2	2
69	2	2	2	2
71	2	1	2	2
73	2	2	2	2
69	1	2	2	2
73	2	2	2	2
65	2	2	1	2
64	2	2	2	2
74	2	2	2	2
65	2	2	2	2
62	2	2	2	2
68	2	2	2	2
67	2	2	2	2
68	2	2	2	2
63	1	2	2	2
57	2	2	2	2
54	2	2	2	2
53	2	2	2	2
52	2	2	2	2
51	2	2	2	2
70	2	2	2	2
72	2	2	2	2
68	2	2	2	2
68	2	2	2	2
63	2	2	2	2
71	2	2	2	2
75	2	2	2	2
74	2	2	2	2
71	2	2	2	2
75	2	2	2	2
70	2	2	2	2
65	2	2	2	2
71	2	2	2	2

73	2	2	1	2
74	1	2	2	2
59	2	2	2	2
71	1	1	2	2
63	2	1	2	2
75	2	2	2	1
73	1	2	2	2
76	2	2	2	2
53	2	2	2	2
56	2	2	2	2
55	2	2	2	2
65	2	2	2	2
74	2	2	2	2
65	2	2	2	2
59	2	2	2	2
69	2	2	1	2
75	1	2	2	2